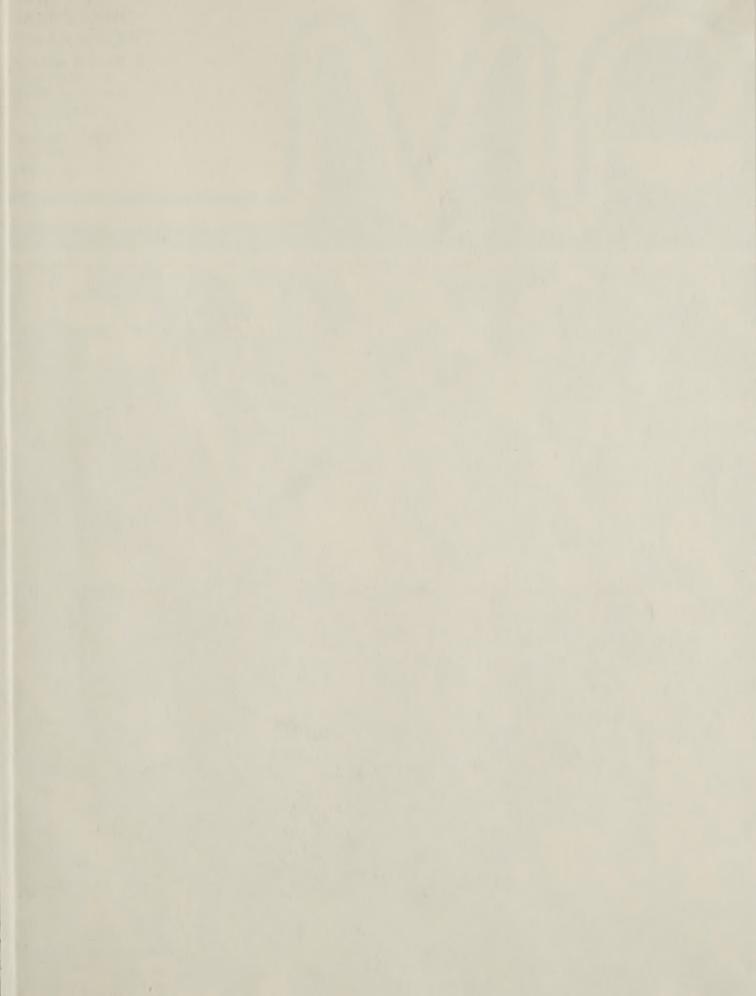




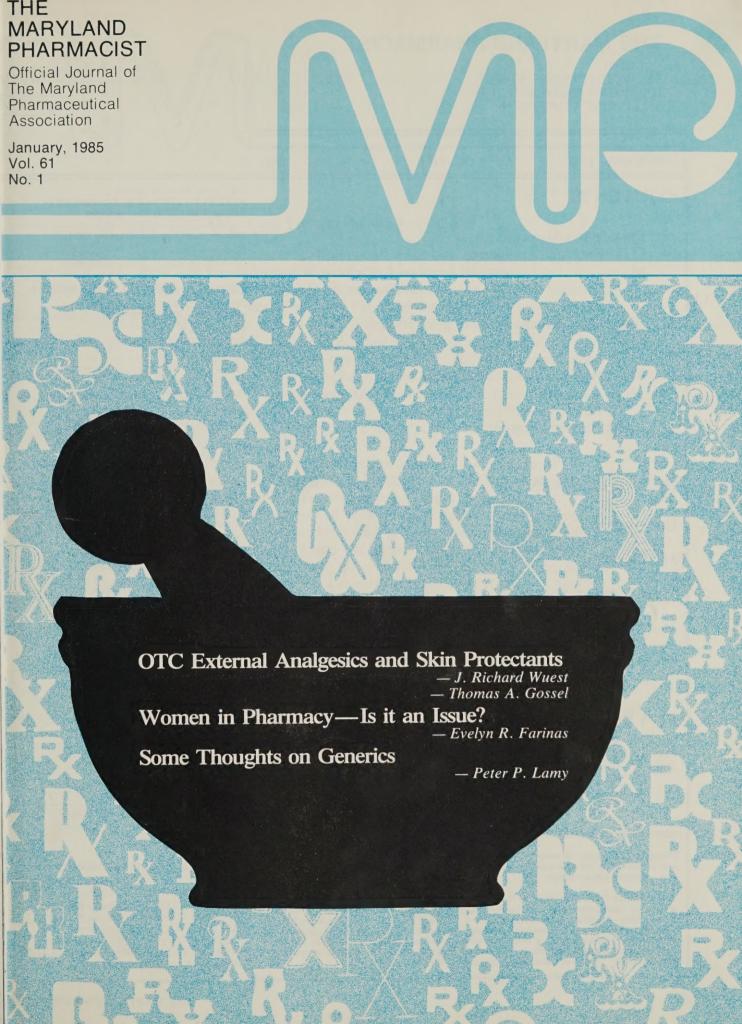


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Where Do We Go From Here?

How time flies—Happy New Year and welcome to 1985!

I hope you had a happy holiday season. But now onto the new business of the new year. Last year I stressed (to the point of overkill, perhaps) the need for communication. I'm sure it will be no surprise if in the new year, my continued commitment is to communication. I have asked (pleaded?) to hear from you on the issues that are vital to you, yet I have received communication from a total of four (yes, four) members of the Association. Four, out of a population of over one thousand members. On a percentage basis, this is less than 0.4% communicative members. Am I to assume (lookout for that word!) that the remaining 900 plus members are happy with everything that the association is doing? I doubt it.

By the time you read this message the Maryland Legislature will be in session. By way of the Newsletter and this Journal, we will keep you apprised of the goings-on in Annapolis. You will have to keep us apprised of how you feel about the bills that are presented. Remember, today it is a bill, tomorrow it is a law. Bills can be lobbied and changed, laws require a great deal of effort to get changed. You can be sure that the Association will be at the forefront, keeping an eye on bills affecting both the profession and business of pharmacy. I hope we can count on you for your support in Annapolis. If you can help by contacting your legislators, especially if you are personally acquainted with them, please let us know.

As I have said before, if we don't have your opinion, we cannot successfully represent you, either in Annapolis or anywhere else. Let us hear from you!

Sincerely yours,

Ronald A. Sanford, P.D.

PRESIDENT 1984-85.

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. I, NO. 11

Advising Consumers on OTC External Analgesics and Skin Protectants

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Goals

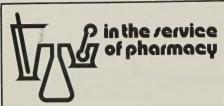
The goal of this lesson is to:

 review the pharmacology and therapeutics of OTC external analgesics and skin protectants.

Objectives

At the completion of this lesson, the successful participant will be able to:

 choose the appropriate external analysics and skin protectants for treating minor dermatological disorders;



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- explain the proper technique for applying these OTC agents;
- 3. decide when the consumer should be referred to a specialist.

Introduction

Previous lessons in this continuing education series have stressed that OTC drug product ingredients are being studied for safety and efficacy. These studies have been underway for over a decade, and have been responsible for numerous exciting changes occurring in the OTC marketplace.

The areas of external analgesics and skin protectants are no exception. Pharmacologic agents used for these purposes have also been investigated. Some of the external analgesics and skin protectants have been discussed in other portions of this lesson series. Because of their widespread use and importance, this month's lesson will be an in-depth discussion of these two groups of agents. Many of these OTC ingredients that have been proven to be safe and effective have been used for hundreds of years. When one reads that the OTC market is rapidly changing (and it is), this doesn't automatically mean that the old is being replaced with the new. Rather, it means that the ingredients are now used with confidence and that they safely exert the claimed actions.

External Analgesics

External analgesics are agents which are applied to the skin to relieve pain, itching and/or irritation. Three pharmacological classifications of drugs are included in this group: topical analgesics, antipruritics and local anesthetics. An important point to remember is that these agents do not actually treat disease. Instead, they alleviate the symptoms of localized disorders caused by irri-

tants such as trauma, chemicals, allergens, toxins, ultraviolet light and thermal burns, insect bites, or certain systemic diseases such as arthritis:

The overall category of external analgesics can be subdivided into three groups. The first contains those drugs that depress the skin's sensory receptors. The second group is comprised of agents that stimulate these cutaneous receptors. Members of this latter group, the counterirritants, distract the individual's attention from deeper-seated or more intense pain by inducing a feeling of coolness, warmth or mild irritation to the skin. In this manner, counterirritants relieve muscle, joint, bursal or tendon pain. If the agent increases blood flow to the area, it is called a rubefacient ("bring-on redness"). A third subgroup of external analgesics, i.e., camphor and menthol, performs both actions. At low concentrations, these agents depress sensory receptors while at stronger concentrations, they exert counterirritant activity.

To understand how external analgesics work, one must first briefly review the basic concepts of pain and itching, and recognize how they dif-

Pain is hard to define and subjective because it is interpreted individ ually. Additionally, it is almost im possible to explain to another persor what the sensation actually "feels' like, in terms that the other person can experience in the same manner As pain relates to skin, there are dermal receptors that are specific fo cold, pain, pressure, touch and warmth. Each is totally differen from the other in that it can only per ceive its specific sensation. The pair receptors are those nerve ending that accept "painful" stimuli an transmit them along to larger nerv fibers, to nerve trunks, to the spine cord, and finally, to the brain. It is es timated that there are, on the aver age, approximately 4000 pain receptors per square inch of skin surface. They are anatomically and biochemically less complicated than other types of sensory receptors, and therefore, are more readily affected by stimuli, as well as external analgesics. Table 1 lists each of the various sensory receptors in the skin and states how they are affected by external analgesics.

TABLE 1 Sensory Receptors in the Skin

1. PAIN:

Bare nerve endings highly penetrable by drugs.

2. COLD:

(End bulbs of Krause): less penetrable but can be blocked by external analgesics. Can also be stimulated by counterirritants and mask the sensation of pain.

3. PRESSURE:

(Pacinian corpuscles): can be blocked by external analgesics but at a much higher concentration than that needed for pain.

4. TOUCH:

(Meissner's corpuscles): can be partially or completely blocked by external analgesics depending on the concentration that reaches them.

5. WARMTH:

(End organs of Ruffini): can be partially or completely blocked by external analgesics depending on the concentration that reaches them. Like cold receptors, can be stimulated by counterirritants to mask the sensation of pain.

The way each person experiences pain is learned, rather than inborn. People react to painful stimuli based on past experiences. We train ourselves to specific psychological hresholds for each type of stimulation.

Deep-seated pain originating in he muscles, joints and internal organs is "duller" than surface pain, and spreads to adjoining and distant issues. For example, the pain of angina which is centered in the heart's muscle, is often "referred" to the arm or face. Arthritic pain in a joint may induce spasms and pain in its supportive muscle. The "stiffness" that accompanies arthritis is frequently

not only a function of the inflammatory response, but also the body's attempt to immobilize and prevent further damage to the diseased joint.

Pain is almost always associated with psychological and emotional factors, and is invariably associated with anxiety. For this reason, the placebo effect cannot be disregarded. The thought that the persons (and others) are "doing something" to relieve pain, e.g., rubbing the product on the skin, contributes greatly (sometimes totally) to the therapeutic effect of the medication used.

Itching. Even though itching is one of the most commonly experienced sensations and oftentimes more annoying than pain, its exact physiology has not yet been fully determined. Physiologists agree that both pain and itching are transmitted along the same neural pathways. The difference in perception seems to be one of degree, with itching the outcome of lower intensity stimulation. In other words, the sensation of itching could very well represent a milder form of pain. Notwithstanding the similarity between pain and itching, the response to them is totally different. We try to "get away" from pain and "go after" an itch by scratching.

The FDA advisory panel that reviewed these drugs defined topical analgesics as agents that, after penetrating the skin's outer layers, enter into nerve endings and block the perception of pain. Some prevent pain development without causing numbness of the electrical impulses that would have sent the sensations of pain to the brain. Others mask pain by counterirritation as explained earlier. Still others reduce swelling (i.e., hydrocortisone) or block the action of trauma-released inflammatory substances (i.e., antihistamines).

The panel's definition of topical anesthetics was worded very similarly to that of topical analgesics, with only a fine line of distinction between the two. This group completely blocks pain receptors and causes numbness. Topical anesthetics block other sensations as well.

Topical antipruritics (anti-itching) are also similar to the other groups. There is overlap between the various types of external analgesics. Anti-

pruritics act by inhibiting the local effects of histamine or other chemical mediators, or by directly suppressing pain receptors.

Safe and Effective Drugs. Table 2 lists OTC external analgesics that the FDA advisory panel ruled to be safe

and effective.

TABLE 2 Safe and Effective OTC External Analgesics*

1. ANALGESICS/ANESTHETICS/ ANTIPRURITICS

Benzocaine
Benzyl alcohol
Butamben picrate
Dibucaine (+ HCl)
Dimethisoquin HCl
Diphenhydramine HCl
Dyclonine HCl
Hydrocortisone (+ acetate)
Juniper tar
Lidocaine (+ HCl)
Phenol (+ Phenolate Na)
Pramoxine HCl
Resorcinol
Tetracaine (+ HCl)
Tripelennamine HCl

2. COUNTERIRRITANTS Allyl isothiocyanate Ammonia water, stronger

Capsicum Histamine dihydrochloride Methyl nicotinate Methyl salicylate Turpentine oil

3. AGENTS WITH BOTH ACTIONS Camphor Menthol

*As determined by an FDA OTC advisory panel

Several agents depress nerve endings. These include the local anesthetics, benzyl alcohol, juniper tar, phenol and resorcinol. Benzyl alcohol is a constituent of Peruvian balsam, tolu balsam and storax which, along with juniper tar, have been used for decades as external analgesics for treating itching of eczema, psoriasis and other dermatoses.

Lister described the action of phenol more than 150 years ago. Since then it has been used for a number of purposes including antibacterial, antifungal, keratolytic, cauterizing, and antipruritic activities. There is no doubt that it is toxic when used undiluted, and its effectiveness as an antimicrobial is now being questioned since the introduction of newer, safer drugs. However, used in a 0.5 to 2% concentration (never more because it is too irritating and necrotic to tissue), phenol penetrates the skin and exerts a local anesthetic effect on sensory nerve endings somewhat similar to benzocaine.

An exception to the above comment on concentration is phenol mixed with camphor. The liquid (eutectic) that forms actually modifies the severity of phenol's necrotic action on the skin. Camphor seems to have some kind of a physical phenolholding effect. With this in mind, even though the upper limit of solutions containing phenol alone is 2%, combinations containing up to 4.7% phenol and 10.8% camphor have also been ruled to be safe and effective for OTC use. However, all phenol-containing products must bear the warning: "Do not apply this product to extensive areas of the body or under compresses or bandages" due to the potential toxicity of excessive use or occlusion.

Resorcinol is a phenolic compound that resembles phenol in its effect, but is much less toxic. It, too, is a safe and effective OTC external analgesic, used in a 0.5 to 3% concentration..

Diphenhydramine and tripelennamine were also ruled to be safe and effective external analgesics due to their antihistaminic effects. Histamine is a chemical (hormone) that is usually bound to mast cells, the lungs, and white blood cells. In its storage component, it is dormant and unreactive. However, when an antibody-antigen complexation reaction occurs, histamine is released from storage. It then binds to histamine-specific receptors in smooth muscle and exocrine glands. In essence, this is what causes the itching and wheals of rash (urticaria), and the increased lacrimal and nasal secretions associated with colds, hay fever and allergic disorders.

Antihistamines, as their name implies, inhibit the action of histamine. They do this by binding to histamine-specific receptors and blocking the entrance of histamine. In the case of itching, this binding results in their antipruritic action.

Antihistamines are more effective for generalized or extensive itching when taken orally. However, diphenhydramine hydrochloride (1 to 2%), and tripelennamine (0.5 to 2%) have been ruled to be safe and effective OTC topical antiprurities for localized itching. The sooner the product is applied after itching begins, the more likely it will be effective. This is true because once histamine binds to its receptors, it is difficult for antihistamines to displace it. On the other hand, since antihistamines are not appreciably absorbed into the systemic circulation after topical application, there is little chance of CNS depression and drowsiness.

Hydrocortisone. When hydrocortisone was transferred to OTC status in 1980, it came as a surprise to many people. This is largely because it had been marketed as a prescription-only drug for 30 years. There had been a push to switch hydrocortisone to OTC in 1956, but the petition was refused due to a lack of data which showed safety for self medication, and a need for additional information on percutaneous absorption. In 1979, an FDA advisory panel reviewed more than 90 clinical studies that had accumulated since the introduction of hydrocortisone, and ruled that it is both safe and effective for OTC use. The panel could find only three cases of serious adverse effects reported in over 12,000 closely monitored patients who had received the drug. In each of the three instances, the application of hydrocortisone was excessive. The panel ruled that, with proper use, some hydrocortisone is absorbed through the skin, but so little that systemic effects are unlikely to occur.

In the same manner as other glucocorticoids, hydrocortisone inhibits inflammation and its resulting swelling, tenderness, localized heat and redness. It does this by inhibiting formation of edema, vasodilation and migration of white blood cells into inflamed areas. It also inhibits the action of chemicals that cause the inflammatory response to occur. Reducing inflammation reduces stimulation of pain receptors. The advisory panel ruled that hydrocortisone should be available OTC in its lowest effective strength which has

been determined to be 0.5%. It has been suggested that this be increased to 1%.

Counterirritant External Analgesics

Allyl isothiocyanate is the active principle in volatile oil of mustard. Interestingly, mustard has been used for centuries both as a condiment and a medicine. Allyl isothiocyanate, the active counterirritant principle, does not occur in mustard seed in its active form. The volatile oil is tied up in the seed with a fixed oil along with a glycoside and an enzyme. During processing, the fixed oil is separated from the volatile oil, and when the residue is macerated in warm water, the enzyme hydrolyzes the glycoside and allyl isothiocyanate is formed. Even though mustard is used as a condiment and is pungent and acrid, it contains little free allyl isothiocyanate. Therefore, mustard itself is no a counterirritant in the small amoun used to season food. However, ir years gone by, plasters and poultices containing powdered mustard seed deprived of its fixed oil were used They would be moistened in warn water to complete the reaction de scribed earlier.

Today, allyl isothiocyanate is man ufactured synthetically. Both the natural and synthetic forms are powerful counterirritants and are safe for use in 0.5 to 5% concentrations.

Stronger ammonia water in 1 to 2.5% solutions is another approved counterirritant, as are capsicum and turpentine oil.

Histamine, the naturally occurrin hormone discussed earlier, is not elfective orally because it is destroyed in the digestive tract. However, when injected or applied to the skin as the synthetically manufactured histamine dihydrochloride, it cause flushing and warmth similar to the direct application of heat. It is, therefore, included in the safe and effective counterirritant group is strengths of 0.025 to 0.1%.

The vitamin niacin is a vasodilate when taken orally, but it has no suc activity when applied to the skin. I ester, **methyl nicotinate**, readily penetrates the cutaneous barrier and produces a counterirritan

rubefacient effect. It is approved for this use in 0.25 to 1% concentrations.

One of the long-standing counterirritants is **methyl salicylate**. It is also used in small concentrations as a flavoring agent (e.g., wintergreen, teaberry). Topical application causes no toxicity, but the pleasing odor and taste have led to oral ingestion of liquid products by children, resulting in serious poisonings. Therefore, liquids containing methyl salicylate in concentrations exceeding 5% require child-resistant containers.

Based on no reports of fatalities occurring since the tamper-resistant packaging requirement was initiated, the panel ruled that the benefit/ risk potential favors continued OTC availability of methyl salicylate in concentrations up to 60%. The panel felt that there is no benefit from higher strengths. Methyl salicylate is an effective counterirritant, and has demonstrated activity in hypertonic muscles in spasm and painful arthritic joints. However, it has not yet been proven that it is an "analgesic" as the term is defined by the advisory panel. The concept of whether salicylates are effective on topical application will be explained shortly.

Two drugs have been approved for use as both topical analgesics in low dosages, and counterirritants in higher strengths — **camphor** and **menthol**. The respective strengths are camphor 0.1 to 3%, and menthol 0.1 to 1%, as topical analgesics. For counterirritant use, the strengths are camphor 3 to 11%, and menthol 1.25 to 16%.

At lower concentrations, these two agents depress cutaneous receptors. and at the higher strengths they stimulate cutaneous receptors. The net result is pretty much the same, however, in that both are effective for alleviating pain when applied topically. Camphor produces a feeling of warmth along with a mild local aneshetic effect. Menthol, on the other and, stimulates the nerves for perception of cold while depressing hose that perceive pain. The person nitially feels coolness, but this is soon followed by warmth. In both instances, the pleasant "medicinal" roma is an important psychological actor in the overall effectiveness of

the product.

The claims that manufacturers are permitted to make to consumers are listed in Table 3. They can be used as guidelines when recommending these products as well.

TABLE 3 Claims for OTC External Analgesics Suggested by FDA Advisory Panel

- FOR COUNTERIRRITANTS: For temporary relief of minor aches and pains of muscle and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains.
- FOR HYDROCORTISONE: For temporary relief of minor skin irritations, itching, and rashes due to eczema, dermatitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, and jewelry, and for itchy genital and anal areas.
- FOR THE OTHERS: For temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations.

Are Salicylates Effective Analgesics When Applied Topically?

While this is an interesting and important question, its answer is unclear and somewhat controversial. Millions of persons have used topical products containing aspirin or triethanolamine salicylate to relieve "aches and pains". Most swear by the results. However, the advisory panel concluded that, even though there is over 80 years accumulation of documentation that orally administered salicylates are effective pain relievers, similar evidence for topical application is lacking. The exception to this is methyl salicylate, which is a proven counterirritant. For the others, the panel could find no evidence to support the claim that topically applied salicylates interfere with nerve conduction and block the transmission of painful impulses. Nor could it find proof that salicylates exert an antiinflammatory action on the skin, or relieve pain within the skin itself, as do the other external analgesics.

There is no doubt that aspirin and other salicylates relieve pain associa-

ted with injuries to the skin and deep-seated painful conditions — most specifically arthritis and trauma. However, this use relates to a systemic activity involving both central and peripheral effects probably due to prostaglandin inhibition.

There is further proof that aspirin and triethanolamine salicylate are readily absorbed through the skin. Nonetheless, in the panel's opinion, the activity of these two drugs is mediated through their systemic pharmacology, not through a local action. Until the panel receives proof (rather than testimonials) that these drugs are absorbed through the skin in sufficient quantities to provide effective plasma concentrations equal to those achieved on oral ingestion of aspirin, it will not make a final ruling on topically administered salicylates.

The panel report was based on data gathered as of 1974. Studies have been ongoing since then. In the meantime, such products can continue to be sold OTC, and the recent influx onto the market of more of them could mean that the results of the studies are positive.

Skin Protectants

Humans have applied relatively inert "medicaments" to their skin to treat burns, wounds, irritated areas and abrasions since time immemorial. In modern times, these same or similar substances have been used as physical protectants against chemical irritants and to prevent drying and to remove oozing fluids.

The FDA Advisory Panel on OTC External Products reviewed many of these agents and found some to be relatively inert, but psychologically important. Therefore, they ruled them to be safe and effective for continued OTC sale. These substances included petrolatum, cocoa butter, and zinc oxide. The list of skin protectants that are safe and effective for self medication appears in Table 4.

Although the panel indicated that it could not locate any well controlled clinical studies to prove the agents are effective, it nonetheless ruled that they should remain on the market. This was done partly because they have been widely used for so long, and because they are included in all standard drug compendia and

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TABLE 4
Skin Protectants Ruled Safe and
Effective for OTC Use

	CLAIMS		
AGENT	1	2	3
Allantoin	X	X	
Aluminum hydroxide gel			X
Calamine			X
Cocoa butter	X	X	
Corn starch*		X	
Dimethicone		X	
Glycerin		X	
Kaolin			X
Petrolatum	X	X	
Shark liver oil	X	X	
Zinc acetate			X
Zinc carbonate			X
Zinc oxide			X

- Claims can be made that these agents are useful for temporary protection of minor cuts, scrapes, burns and sunburn.
- Claims can be made that these agents help prevent and temporarily protect chafed, chapped, cracked or windburned skin and lips.
- Claims can be made that these agents dry the oozing and weeping of poison ivy, poison oak and poison sumac.
- * other potential claims are astringent, diaper rash, fever blisters and insect bites.

extbooks.

The panel also provided "official" definitions for terms that have been used rather randomly in medical and pharmacy practice for centuries. A quick review is presented in Table 5.

All of the substances in Table 4 are considered to be **skin protectants**, a term which is broadly defined as agents that protect injured exposed skin or mucous membrane surfaces from harmful or annoying stimuli.

To quickly review important feaures of the skin protectants listed in Table 4, it should be noted that alantoin is a purine derivative that has the ability to form complexes with a number of sensitizing agents. t then renders them nonsensitizing. This makes allantoin especially useul for individuals who are hyperensitive to other topically applied products. Allantoin is also keratolytc (skin softening). When applied to he skin, it extracts sulfhydryl compounds from keratin in the epidermal layer. This, in turn, enhances abcorption of moisture into the stratum corneum and softens the skin.

TABLE 5

ABSORBENT: has the properties of absorbing, incorporating, sucking up and/or taking up liquids, gases and light rays into itself.

ADSORBENT: attracts and holds liquids, gases and suspended particles to its surface.

ASTRINGENT: has little ability to penetrate cells, but instead, acts on cellular surfaces to precipitate protein materials and thus render them less permeable to the passage of chemicals.

DEMULCENT: a protective agent applied to skin or mucous membranes to alleviate irritation.

EMOLLIENT: is a bland, oleaginous substance that causes mucous membranes and skin (intact or damaged) to be softer and more pliable.

LUBRICANT: a substance that lessens the friction between skin and touching skin or other surfaces.

Aluminum hydroxide gel (the same as that used as an antacid) is a useful skin protectant and astringent. Its action is thought to be due to the aluminum ions which bind to protein on the skin's cellular surface. Aluminum hydroxide gel reportedly provides relief from ringworm, impetigo, prickly heat, weeping eczema and other skin conditions.

Calamine is basically zinc oxide that is colored red with ferrous oxide. Its therapeutic effect is due totally to the zinc oxide component since ferrous oxide has no topical pharmacological effect. It is discussed in more detail in a previous lesson in the series, "Poison Ivy/Oak Reactions and Their OTC Remedies".

Cocoa butter is a bland, fat-based emollient that provides a physical barrier against further contact with the skin and irritants.

Corn starch is a drying agent and lubricant. It is unreactive with skin, but affords protection by absorbing moisture and reducing friction between areas of the skin that rub together. Corn starch also absorbs and suspends toxins and microorganisms, keeping them from contact with the skin. The advisory panel reported that many authorities consid-

er corn starch to be superior to talc for its drying activity. It is commonly used in diaper rash products, to be reviewed shortly.

Dimethicone is a silicone compound that almost completely seals wounds and irritated skin, preventing further drying. It is recommended for windburn, chapped skin and cracked lips, but not for wounds that may be infected. In this instance, sealing the wound would lead to a worsening of the infection.

Dimethicone also adheres to the skin and is water repellent. This property protects skin from exposure to water soluble irritants and sensitizers. It is often used in diaper rash products to prevent ammonia in the urine from coming into contact with baby's skin.

Glycerin, covered in more detail in the lesson entitled, "Counseling Consumers on Dry Skin," is an excellent humectant. However, in a 50% or less solution, it will give up water to the epidermis and soften the skin.

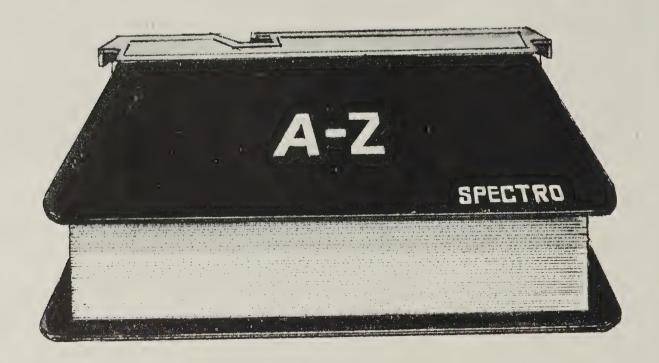
Kaolin is an effective absorbent for use as a dusting powder on weeping eczemas and oozing skin conditions.

Petrolatum is both emollient and lubricating. Applied to clean wounds, it prevents evaporation of fluid, excludes the entry of bacteria and irritants, and reduces pain. Petrolatum is the vehicle for most topical ointments. It also finds wide usage in preventing diaper rash. According to the advisory panel, the only real difference between white petrolatum and yellow petrolatum is the color.

The panel had little to say about shark liver oil other than agreeing it is a safe and effective emollient. While there are no studies available, it has been used for years to successfully treat burns and hemorrhoids, and to prevent diaper rash.

Sodium bicarbonate was also ruled to be an effective absorbent even though it does not fit neatly into the dryness/wetness/lubricant categories ruled on by the panel. It has been a widely used folk remedy for treating insect bites, hives, chicken pox lesions, and minor burns, including sunburn. In each instance, it relieves pain and itching. Sodium bicarbonate baths have also been used to treat eczema and exfolliative dermatoses. The exact mechanism is

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not known, but bicarbonates do combine with tissue chemicals to form alkaline albuminates, and with surface fats to form soaps. The resultant softening of the epithelial tissue may be responsible for its anti-itching activity.

Because of its popular use, FDA reassigned the review of sodium bicarbonate to the "miscellaneous" OTC panel for a full report on its actions and usefulness in treating dermato-

logical conditions.

Zinc acetate is an astringent. It and other soluble zinc salts (chloride, sulfate, etc.) precipitate protein and are common ingredients in antiperspirants. Zinc oxide and the nonionizable zinc salts (carbonate, stearate, etc.) are only slightly astringent. However, they are effective absorbent and lubricating agents. Zinc oxide finds wide use in treating diaper rash and prickly heat, eczema, impetigo, ringworm, itching and psoriasis. It is also a complete sunblock agent.

Zinc oxide, petrolatum and other skin protectants are popularly used for preventing diaper rash. This is a common problem in infants and bedridden and incontinent geriatric pa-

tients.

The major contributors to severe diaper rash are prolonged wetness, contact with bacteria and fungi, and occlusion provided by plastic diapers, diaper covers or incontinence pants.

Because of moisture, heat, and occlusion, microorganisms that normally thrive on fecal materials, now proliferate even more and metabolize urine to ammonia. This irritates the skin. Lesions form which allow entry of bacteria and fungi which worsen the condition even more. The use of antifungals and hydrocortisone are discussed in other lessons. Prevention of diaper rash is the best advice. Frequent diaper changes, thorough washing of the area, reducing total occlusion as much as possible, and applying skin protectants are helpful. These agents act as a physical barrier to irritants and microorganisms, and in the case of insoluble zinc salts and corn starch, take up moisture and thereby reduce skin maceration.

Unsafe/Ineffective Skin Protectants

Because of their popular use in the past, and because the advisory panel ruled they were unsafe and/or ineffective as skin protectants, a few words should be presented on bismuth subnitrate, boric acid, sulfur and tannic acid.

The danger of bismuth subnitrate use is that it is potentially toxic when swallowed. Bacteria in the intestine convert nitrate to nitrite which is then absorbed. On entry into the blood, nitrites cause methemoglobinemia, a condition characterized by hemoglobin that has its iron component oxidized to the ferric form. As such, it cannot transport oxygen. Bismuth subnitrate has caused fatalities in infants. The panel ruled that it is of questionable efficacy as a skin protectant and has a poor benefit/risk ratio.

Since its introduction by Lister into medical practice in the late 1800's, boric acid has attained immense popularity. However, data have also accumulated to show that it is toxic both when swallowed and when applied in sufficient concentration to damaged skin. Fatalities have occurred from oral injestion of as little as 20 gm, in adults and 5 gm. in infants. While it is an excellent buffer for eye drop preparations, the therapeutic value of boric acid is now under considerable questioning. The panel reported that boric acid has no specific therapeutic value when it is applied to the skin.

For many years **sulfur** was considered to be non-toxic. The panel stated that recent information now points toward a toxic, hazardous association with the topical use of sulfur. Sulfur can be absorbed through damaged skin. Once in the blood, a significant portion can be converted into hydrogen sulfide, a poison.

As far as its effectiveness in treating burns, abrasions, wounds and other skin conditions is concerned, the panel ruled that not only is its value unsubstantiated, but sulfur actually injures skin because it breaks down the epidermis. While this effect is useful in treating acne, its use as a healing agent or skin protectant

was unacceptable to the panel. Paradoxically, the advisory panel that reviewed its use as an anti-acne agent ruled that sulfur is safe and effective for OTC topical use in treating acne lesions. This is a visible dichotomy that FDA will soon need to resolve.

Tannic acid has long been used topically in treating burns. Internally it has been included in the once popular "universal antidote". It is now known that tannic acid can cause poisoning via topical and intestinal absorption because it depresses liver function and destroys hepatic cells. It is also deposited in muscle, lung and kidney tissues. The original claims for tannic acid were that it precipitated protein, acted as a protective coating, excluded air, and relieved pain. This is the mechanism for astringents, but the "protective coating" that tannic acid allegedly provides is an outer crust under which bacterial growth can flourish. The advisory panel concluded that, due to documented hepatotoxicity and obsolete indications, tannic acid is not acceptable as an OTC skin protectant.

Conclusions

In summary, the panel ruled that those medicaments listed in Table 2 are safe and effective external analgesics. The same is true for the skin protectants listed in Table 4. All of these agents can be recommended for OTC use in self medicating the minor ailments presented in Tables 3 and 4. On the other hand, the benefit/risk ratio of bismuth subnitrate, boric acid, sulfur and tannic acid may weigh too heavily towards the risk side, and these agents should not be used in therapy.



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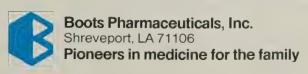
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JANUARY, 1985 13

Comparative bioavailability data available on request **Redbook, August 1984.

Women in Pharmacy— Is it an Issue?

Evelyn R. Farinas, Pharmacist

On November 17, 1984, the Virginia Pharmaceutical Association sponsored a symposium on "Women in Pharmacy: Active, Inactive or Inert." While this meeting did not provide divine inspiration, nor did anyone promise to part the waters of the James River so that we women pharmacists could reach the promised land, I am very glad that I went. I liked the people I met, the ideas presented by the panelists, the rebuttals that came from the audience, and even the questions that went unanswered such as the input of the pharmacists in biomedical ethics.

I want to share with you first a summary of the ideas and discussions presented at the seminar; and follow up with opinions I collected from an informal poll of pharmacists, men and women, concerning this matter. The consensus was that the issues discussed belong to the profession as a whole, and not just to women in pharmacy.

The keynote speaker was Dr. Marvin Shepard who set the stage by addressing topics such as the increasing enrollment of women in pharmacy schools, the significantly small number of women in faculty and managerial positions, the drift of women pharmacists into hospital pharmacy practice, and the lack of substantial women pharmacists participation in local professional associations. Dr. Shepard indicated more studies are needed to identify the reasons why pharmacists, regardless of sex, are dropping out of the profession, and why men are selecting out of pharmacy as a professional choice.

The panelists presentations and the discussions that followed really explored two basic ideas: (1) how women pharmacists cope with the demands of their jobs and (2) is the profession changing and how are women reacting to the changes?

Goal-setting, prioritizing, time management and networking are concepts that do not apply to women only, although working women are now putting these concepts to work for them. Conflicts resulting from alternating shift schedules, dual career families, and lack of spouse and family involvement in sharing the responsibilities of home caring are not unique to our profession. Some possible solutions are job sharing, flex-time, work-site day care centers, and parttime employment

with full or partial benefits. And of course, no seminar dealing with self improvement would be complete without a few pointers on image building. That is not to say that we must all "dress for success" in our three piece suits, but that we should try to project an image of competency and to maintain it on a daily basis.

Unfortuantely no one said the "sky is the limit" about our professional future. What they did say is that women are increasing their numbers in all the health professions and it is projected that by the year 2000 women will make up 40% of all pharmacists. Pharmacists roles will increase in the areas of clinical services and drug information; yet in order to move into government and industry, pharmacists should pursue advanced degrees. Nesbitt's megatrend philosophy of "high tech/high touch" was translated into pharmacy as making ourselves available to the patients on a personal level even though the public is demanding more technical information from us.

Margaret Heckler, H.H.S. Secretary was quoted as saying that pharmacy has less control over its own destiny than any other profession. Pharmacy is impacted by physicians, nurses, the public third party payors and the government. Issues such as reimbursement for clinical services, PPO's, DRG's, establishing a third class of drugs, and shifting drugs from RX to OTC classification impact the way we practice yet there is little we can do about them. Crime certainly affects the way we practice, and it was only recently that the federal government took positive stops to deter pharmacy crime. To gain more control it was emphasized that pharmacists should join and actively participate in their local and national organizations. We need to act, not react.

Influenced by TV and by the recent elections, I decided to conduct my own "exit poll." I asked 3 questions: What was your overall reaction to the program, Who or what idea influenced you most? and Will you change the way you practice as a result of this meeting? Well, much like the presidential debates, the answers had nothing to do with the questions. By far, the majority had a positive attitude about the meeting, but I'd like to present here more of the critical answers such as:

(a) the panelists were too far removed from actual retail or hospital practice to know what the real problems are.

Evelyn Farinas is a hospital pharmacist. She practices at the National Institutes of Health, Clinical Center, Bethesda, Maryland.

- (b) I expected but did not get practical, how-to solutions to the problems that we face daily.
- (c) I do not feel comfortable speaking in a large group so I did not participate in the Question and Answer session.
- (d) The turnout wasn't as large as I expected; publicity should have been better.
- (e) It is hard to keep up a professional image when you have to sweep the floors, stack the boxes and operate the lottery machine.

A male pharmacist who could not attend, expressed dismay that spouses had not been invited. He feels that pharmacists are their own worst enemies because the issues facing our profession are not just about men and women in pharmacy, but rather the issues are increased specialization within the profession, appropriate reimbursement for services rendered, and improving the quality of pharmacy education.

What do you think?

This and That About Pharmacy

by Leon Weiner, P.D.

Personal Observations of Pharmacy in Pikesville late 1984

Shapiro's Food Market, located at Reisterstown Road and Old Court Road, has announced that they will be opening a pharmacy at that location in November 1984. Public will have to change their prescription habits as Shapiro's is closed every Saturday and all Jewish holidays.

One block east on Old Court Road, Giant Food and Pharmacy #1090 has doubled in size and remodeled completely. At certain times, it is still very hard to find a parking space at this gold mine location. Pharmacists Herb Sachs and Martin Paul are so busy counting pills that they have a hard time getting time off for their vacations.

Five blocks farther east on Old Court Road, pharmacist Phil Weiner, of Weiner's Professional Pharmacy, is carefully observing what is going on in his neighborhood as he walks around his store with his earphones on and taking good care of all his customers. By the way, this is the same Phil Weiner who can be heard over radio station WCAO-AM at 6:30 a.m. and WXYZ-FM at 8:00 a.m. each Sunday morning broadcasting the Pharmacy Public Relations Program "Your Best Neighbor".

Eight blocks south on Reisterstown Road, landmark Field's Pharmacy is quite active with two lovely young pharmacists on duty most of the time. They are Jolanta Peretz, UofMD Pharmacy 1979, and Sylvia Glazer, UofMD Pharmacy 1983.

Mark Mallach, also known as "The Running Doc", is the fulltime pharmacist at Drugfair, 17 W. Baltimore Street, in downtown Baltimore. Genya, his wife is a full time student at UMBC. Mark, UofMD Pharmacy 1979, and his wife have two young children, Elena, age 5 and Ester, age 2. In the fall of 1979, Mark began serious running because he was a new graduate, a new dad, and grossly out of shape after seven years of college. Over the next two years, he ran consistantly and lost close to 50 pounds. He began to average 40 to 50 miles per week. In August 1980, Mark ran the Annapolis 10 Miler in a personal record time. However, he injured himself and by the end of 1981, he was no longer running. The weight began to return. In July 1983, Mark started to run again and by August 1984 was averaging a more conservative 20 to 25 miles per week. He once again completed the Annapolis 10 Miler, but in a slower, healthier time. He is currently training for the Marine Corps Marathon which will take place in Washington, DC, Mark advised me that the benefits of his running, besides physical and psychological, are also professional since the reading involved with running and exercising leads to a ready source of advise to patients on diets, exercise, and sports medicine.



Annette Schonfeld

It has been said "Nice guys (or gals) don't come in first." An exception to this rule is Annette Schonfeld, a kind, sincere human being, who has recently been the subject of articles in a Baltimore weekly magazine and the daily newspaper. Annette, designated as "A Mitzvah* Person", has been elected president of the auxiliary to Baltimore County General Hospital for 1984-1985. For over 16 years, she has been a volunteer at the hospital and served as chairman of the hospital gift shop sponsored by the auxiliary. Working with a team of volunteers, Mrs. Schonfeld anticipates enough sales this year to pledge the hospital about \$50,000 which will be used for equipment and services not figured into the hospital budget. Annette is married to Gerald Schonfeld, UofMD Pharmacy 1951, who has owned Monument Pharmacy in East Baltimore for many years. They have a 27 year old son, Stephen Brian, who graduated from the Massachusetts College of Pharmacy in 1981 and works with his dad at the pharmacy.

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^{(*}Mitzvah—Webster's Dictionary defines as a meritorious act or a good deed.)

Get Well Wishes to:

- 1. Herman Glassband, Hampden Pharmacy, who was wounded in a robbery on November 17, 1984
- 2. Bernard Anoff, Drugfair, and Stephen Needel, Chandler's Pharmacy, both of whom have had major surgery

PHARMACY CHANGES—October 1984

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Owens Pharmacy 2661 Riva Road Annapolis, MD 21401

Drug Emporium 7780 Riverdale Road New Carrollton, MD 20784

Mount Airy Pharmacy 1 N. Main Street Mount Airy, MD 21771

Dart Drug #290 5416 Annapolis Road Bladensburg, MD 20710

Pathmark Super Drug 801 Goucher Blvd. Towson, MD 21204

Twin Knolls Pharmacy 9105L All Saints Road Laurel, MD 20707

Medicine Shoppe 6501 Reisterstown Road Baltimore, MD 21215

CHANGES IN OWNERSHIP

Klotzman Pharmacy 1041 Edmondson Avenue Baltimore, MD 21223

CLOSED PHARMACIES

Manheimer Pharmacy 2502 Eutaw Place Baltimore, MD 21217

Citizens Pharmacy II 601 S. Union Avenue Havre de Grace, MD 21078

Jessup Central Pharmacy Box 535 Jessup, MD 20794

A THIS & THAT FLASH

by Leon Weiner, P.D.

Pharmacist Herman Glassband, 49, is recuperating at Union Memorial Hospital in Baltimore after emergency surgery on his jaw. Glassband, a 1957 University of Maryland Pharmacy graduate, was shot Saturday night, November 17, 1984 in a unsuccessful robbery attempt. Before buying his Hampden Pharmacy, Herman was a detail man for Geigy Laboratories. He lives with his wife, Marsha, and children in the Greengate Development in Baltimore County. All who know Herman wish him a speedy recovery. I personally know Herman from Pharmacy School and I can not use enough adjectives to describe him. Mild spoken, kind, considerate and never to say a bad thing about someone. That's Herman and more. Good Luck, Doc!





The above six men have a couple of things in common. They are all pharmacists who graduated from the University of Maryland School of Pharmacy. In addition, they are also graduates of Patterson Park High School in East Baltimore. Shown at their first informal meeting at Jack's Famous Delicatessen are from left to right:

Tony Petralia, U of MD Pharmacy 1952, Giant Pharmacy Ferdinand F. Wirth, Jr., U of MD Pharmacy 1952, Good Samaritan Hospital

Ronald Maggitti, U of MD Pharmacy 1962, Drugfair William Weiner, U of MD Pharmacy 1944, Spectro Drug Leon Weiner, U of MD Pharmacy 1958, Drug Control Herb Burns, U of MD Pharmacy 1953, Howard & Morris

Next informal meeting is scheduled for Sunday, March 17, 1985 at Jack's Deli. For information, call Willy Weiner at 485-8100 or Herb Burns at 744-1400.

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JANUARY, 1985

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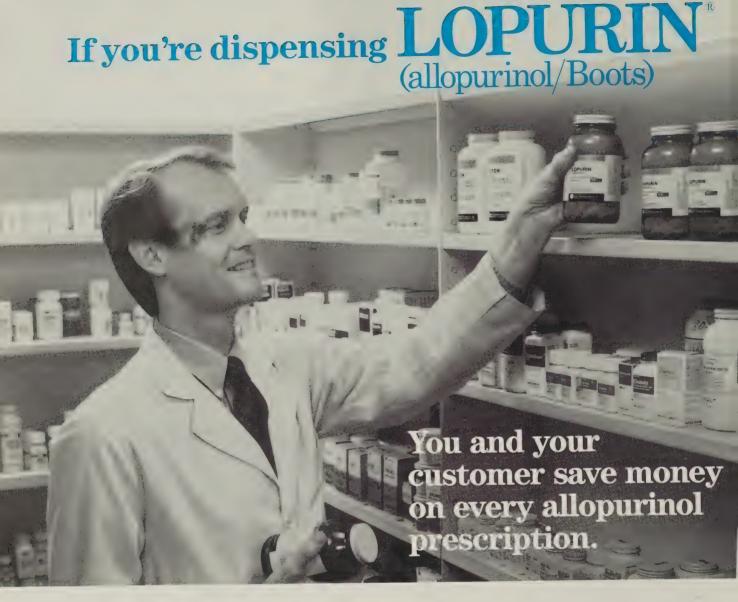
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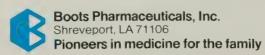
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NARD Plans Multiple Store Seminar

The National Association of Retail Druggists has announced plans for the first NARD Multiple Locations Conference. The Conference, devoted to addressing the needs of those pharmacists who own more than 1 pharmacy, will be held February 21–23, 1985 at the Sheraton Scottsdale Resort, Scottsdale, Arizona.

NARD Executive Committee Chairman Charles M. West noted: "NARD has long recognized the importance of serving the needs of those pharmacists who own pharmacies in multiple locations. This recognition led to the establishment of the NARD Committee on Multiple Locations. That Committee has been advising the NARD Officers, Executive Committee and staff."

ASPL at APhA HMO's and PPO's

Attendees of the upcoming Annual APha Meeting in San Antonio in February will have the opportunity to witness an interesting and informative symposium entitled "HMOs and PPOs: Economic and Legal Problems/Opportunities for Pharmacists."

A panel of four experts will address a variety of important pharmacy practice related issues regarding HMOs and PPOs including: the current status of these delivery systems; their future; their effect on standards of practice and quality of care; their potential economic impact on the practice of pharmacy; whether pharmacists should participate or not; and the legal issues associated with pharmacists forming and contracting with these delivery systems. At the conclusion of the presentations by the panel, members in the audience may participate in a question and answer session.

The Symposium is sponsored by the American Society for Pharmacy Law (ASPL) and the Economic, Social and Administrative Sciences (ESAS) Section of the Academy of Pharmaceutical Sciences. The Symposium will be held on Tuesday, February 19, 2:30 p.m. to 5:30 p.m. in the Four Seasons Hotel, Hidalgo Rooms B&C.

For more information on this Symposium contact Richard R. Abood, J.D., President, ASPL, School of Pharmacy, University of Wyoming, Laramie, WY 82071; Ph(307) 766-6126; or Paul A. Holberg, Ph.D., Chairman ESAS Program Committee, Boots Pharmaceuticals, 6540 Line Ave., Shreveport, LA 71106.

Maryland Poison Prevention Week—1985 MARCH 17-23, 1985

The focus of this year's Maryland Poison Prevention Week campaign will be Mr. Yuk(C), whose green scowling face has been promoting poison prevention in Maryland for the last ten years. This March, the Maryland Poison Center plans to reemphasize its commitment to the program as both an educational and a promotional means to prevent childhood poisonings. Hopefully, the "Has Your Child Met Mr. Yuk?" poster will be displayed prominently in all Maryland pharmacies. Also, we urge pharmacists to use March as a time to remind their customers, especially those with children and grandchildren under five years of age, to use Mr. Yuk's stickers, safety caps and closures and other poison-proofing techniques (proper storage and ipecac syrup) not only during poison prevention week but throughout the year.

Additional details about Maryland Poison Prevention Week—85 will be in the next *Maryland Pharmacist*.

LETTERS

Dear Dave:



I wanted to take a minute to write to you in order to provide some long over-due praise for one of our Association's Committee Chairmen. Elwin Alpern, Chairman of the Convention and Trips Committee, has done a terrific job over the years planning both the successful annual conventions and the many exotic group travel trips sponsored by the MPhA. The trips have provided an outstanding fringe benefit for our members and Elwin has done a good job of selecting excellent values and interesting locations with the approval of the Board of Trustees. In addition, the group travel trips have become a substantial fund raiser for the budget and has helped the membership committee's efforts by being an attractive activity of the Association. All of these activities represent a lot of hard work for Elwin and yet he receives no direct benefit himself from them. I think he deserves our thanks for his efforts for the

Sincerely, Martin Mintz, MPhA Trustee

Association.

JANUARY, 1985

CRITICAL PATIENTS, CRITICAL DRUGS, CRITICAL DISEASES

Some Thoughts on Generics

by Peter P. Lamy, Ph.D., F.A.G.S.

Introduction

After WW II, all developed countries adopted policies that made access to health care independent of restrictions such as the patient's financial resources. Ever-increasing parts of the population were brought under the umbrella of health insurance, which in the United States was accomplished mainly by the introduction of Medicaid (for the poor) and Medicare (for the aged). Unquestionably, these policies have been successful. There is no doubt that Medicare, for example, has been a vital factor in improving the health of the aged, making it possible for many of them to seek treatment for hypertension, glaucoma, pneumonia, cataracts, and cancer.

Recession, unemployment, inflation, and most of all, increasing numbers of eligible persons and increasing health care costs have forced a re-evaluation of these policies. New policies have been established and are being considered, with a goal to undo or adjust the policies of the last three decades.

The Rising Number of Elderly

If one adds the 22.1 million people in the United States who are 55 through 64 years of age to those 26.8 million who are 65 years of age and older, they already make up 21 percent of the population. By the year 2000, those 65 years of age and older will constitute 20 percent of the total population. The US Census Bureau recently projected that the very old, those 85 years of age and older, of whom there are now 5 million, will number 10 million by the year 2000. Given current benefits, they would consume \$85 billion in federal support by the year 2000.

The Rising Health Care Costs

The need for a re-evaluation of established health care policies is underscored by the rising availability and use of "high-tech" medicine and by the higher cost of health care in general. Yet, medical care, however intense, does not necessarily produce health.

Right now, in the United States, we spent one percent of the gross national product on the 1.3 million elderly in the last year of life, a figure that exceeds all monies spent in the country on institutionalized mentally ill and retarded and on all basic and applied medical research.

National health care expenditures are projected to increase during the balance of this decade at an average annual rate approaching 12 percent. By 1990, they could reach \$755.6 billion or 12 percent of the gross national product. It has also been estimated that if health care costs continue to rise as they have since 1900, by the year 2000 the entire gross national product would be consumed by the price of health care. US spending for nursing home care is projected to increase by 121.4 percent to \$67.1 billion by 1990, up from an estimated \$30.3 billion during 1983. An analysis of health care costs in the United States and other developed countries clearly shows that the costs of inpatient hospital care, the cost of ambulatory treatment, and the supply of drugs are by far the most expensive cost factors.

What To Do?

One response to the rising health care costs has been the development of what has been called the new medical-industrial complex. Profitable networks of health care facilities operated by investor-owned corporations are replacing not-for-profit hospitals, nursing homes and other traditional forces as dominant forces in the health care field.

Another approach is that chosen by federal and State governments, all of whom are considering or instituting cost-containment measures.

One instrument to achieve change is the use of copayments by the patient at the time a particular health care service is needed. This policy is based on the assumption that it would make individuals more cost-conscious and also restrain the quick recourse to health care provision for what may only be a trivial problem.

A major attempt is the establishment of social

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly and Chairman, Department of Pharmacy Practice and Administrative Science, School of Pharmacy, University of Maryland at Baltimore, Baltimore, MD 21201.

HMOs, favored by Secretory of HHS Heckler, but not favored by the Office of Management and Budget. Another major attempt, of course, at cost-containment and of restructuring health policies is TEFRA and the DRGs. While it is claimed that they "are working", it is also claimed that many aged might find themselves discharged from acute care hospitals without sufficient community resources to sustain recovery or even without having completely recovered from their illness.

Another "cost-control" attempt may well be the accelerating switching of prescription drugs to OTC status. This attempt meshes very well with increased consumer desires towards "self-care" and "wellness" awareness. This may lead to unanticipated problems such as encountered with a bronchodilator and to a massive increase in use of some drugs. For example, the use of hydrocortisone in external form has increased by about 400 percent since that dosage form was made available as an OTC product. Consumers may seek different avenues of relief. Representative Claude Pepper, who headed a four year study of health care fraud, reported that Americans spend \$10 million yearly on "treatments" that may actually worsen their illness. Elderly, it appears, are particularly susceptible as they seek help against cancer, arthritis, and the aging process itself.

Mistletoes, Easter lillies, bamboo grass, vegetable oil and ground horse's warts are leading articles sold as "cures" for cancer. For arthritis, bee venom, alfalfa seeds, and even cow manure have found favor, and still other useless products are sold freely to the elderly seeking the "fountain of youth" and cures for prostate problems.

The fundamental problem, though, which cannot be avoided and which must be confronted lies in establishing a clear dividing line between what is desirable from an individual point of view and what is essential to the health care needs of individuals which must be paid by society as a whole. Among those issues is the issues of drug costs.

Limiting the Cost of Drugs: Generics

Few issues in health care have aroused more debate than the cost of drugs. Few doubt the great contribution which drugs have made in the last few decades in the fight against previously untreatable diseases. Has that "golden age" come to an abrupt halt in the dispute of costs?

Can drug costs be reduced and is there a risk to patients?

The American Medical Association House of Delegates, meeting in December 1983 in Los Angeles, accepted a report from the AMA Council on Scientific Affairs containing a number of definitions of terms that had been worked out between the American Pharmaceutical Association and the AMA (Table I). All of these terms, which incidentally differ somewhat from the terms used by the FDA, have been used in efforts to

contain drug costs. The major one, and one that might well cause problems to elderly patients, is the one denoting generic dispensing.

Although pharmaceuticals represent a relatively small percentage of total health-care expenditures (about eight percent according to a 1983 Kidder Peabody Research Report), their costs are highly visible and subject to much criticism. One reason often cited is the fact that only about 20 percent of drug costs, according to Pharmaceutical Data Services, are eligible for reimbursement by most health care insurance programs.

The cost of drugs may become even more visible due to recent developments. The 1983 Consumer Price Index shows an overall increase of 3.8 percent. The medical care index rose by 6.4 percent, but prescription drug prices jumped 9.6 percent at the consumer level.

About 40 percent of the top-selling prescription drugs in the United States are now generically available and by the end of the decade, nearly all of the current top 50 drugs will be free from patent restrictions. Generics now account for about 20 percent of all domestic drug sales, and may account for 30 percent by the end of the decade.

Currently, most States deal with either a "positive" or "negative" formulary, and the physician must indicate that a generic can be used or should not be used. Patients can request generic substitutes if they so desire.

This is then essentially a free-market approach, an approach to health care that has often been recommended. Quite often, when it comes to decide whether to purchase either the innovator drug or the generic equivalent, both provider and patient often lack data to make a rational decision, or often do not look past the price, since price differential is most often the only clearly stated fact which is easily perceived.

A free market approach may not be the answer to certain patients, prescribed certain drugs, to treat certain diseases. There are rarely, if ever, knowledgeable buyers. The sick and their relatives, who also may already have reached an elderly age, most often are in no shape to deal calmly, logically, or effectively with the complex and important choices that must be made.

This lack of information on part of the consumer, at least, has recently been highlighted by a CBS-sponsored research project. Of all households polled, 75 percent reported that they are "only somewhat informed" or "not informed at all" about prescription drugs or their illnesses.

Conversely, in a survey recently published in the Journal of the American Geriatrics Society, most of the respondents agreed that "information to clinicians to assess the potential problem of therapeutically inequivalent drug products in the aged was inadequate".

It is not unreasonable to expect increased governmental efforts to increase the use of generic drugs in order to reduce drug costs under Medicare and Medicaid. It is also likely that neither of the current formats,

TABLE I

TERMS DEFINED BY APhA and AMA

1) Drug Product Selection—The act of selecting the source of supply of a drug product in a specified dosage form.

2) Chemical Equivalents—Those multiple source drug products which contain essentially identical amounts of the identical active ingredients, in identical dosage forms, and which meet existing physical-chemical standards in the official compendium, the USP-NF.

3) Biological Equivalents—Those chemical equivalents which, when administered in the same amounts, will provide the same biological or physiological availability, as measured by blood levels, urine levels, etc.

4) Therapeutic Equivalent—Those chemical equivalents which, when administered in the same amounts, will provide the same therapeutic effect as measured by the control of a

symptom or disease.
5) Generic Substitution—The act of dispensing a different brand or an unbranded drug product for the drug product prescribed (i.e., chemically the exact same drug entity in the same dosage form, but distributed by different companies). Examples are:

a) Rufen brand of ibuprofen for Motrin brand of ibuprofen.

b) Unbranded generic ampicillin for Polycillin.

- 6) Pharmaceutical Alternates—Drug products which contain the same therapeutic moiety and strength but differ in the salt, ester or dosage form, and are administered by the same route.
- 7) Pharmaceutical Substitution—The act of dispensing a pharmaceutical alternate for the drug product prescribed. Examples are:

a) Salt—codeine sulfate for codeine phosphate or tetracycline hydrochloride for tetracycline phosphate complex.

b) Ester—propoxyphene hydrochloride for propoxyphene napsylate or erythromycin ethyl succinate for erythromycin estolate.

c) Dosage form—ampicillin suspension for ampicillin capsules.

- 8) Therapeutic Alternates—Drug products containing different therapeutic moieties but which are of the same pharmacological and/or therapeutic class that can be expected to have similar therapeutic effects when administered to patients in therapeutically equivalent doses.
- 9) Therapeutic Substitution—The act of dispensing a therapeutic alternate for the drug product prescribed. Examples are:

a) Chlorothiazide (Diuril) for hydrochlorothiazide (Hydrodiuril).

b) Chlorpheniramine maleate (Chlor-Trimeton) for brompheniramine maleate (Dimetane).

c) Prednisone for prednisolone.

negative or positive formularies, will be employed but that substitution with the least costly generic will be mandated.

Generics: A Short History and Possible Problems

On January 23, 1978, FDA responded to a request from the New York State Health Department to evaluate their list of drug products for therapeutic equivalence. On May 31, 1978, the Commissioner, FDA informed all States that a list was to be prepared of all Rx drug products that are approved by FDA for safety and effectiveness and the Agency's evaluation of their therapeutic equivalence in case of multi-source products that contain the same active ingredient and are identical in strength and dosage form. The list was published in October 1980 and has been revised since then.

Products considered to be therapeutically equivalent are coded "A" but are subdivided into those with no known or suspected bioequivalence problems and those with actual or potential bioequivalence problems resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence.

Just recently, a list of drugs for which FDA's Office of New Drug Evaluation has already granted *paper* NDAs, has been published.

It has been suggested that approval process of equivalents often depends on two few patients (as few as 12, in some documented instances). Furthermore, it is strongly suggested that so-called equivalents may not be equivalent enough:

FDA requirements for equivalency of phenothiazines (Federal Register, August 26, 1980, p. 56838) are as follows:

"The test drug products meets the *in vivo* portion of the bioequivalence requirement in humans if the following conditions are met:

"(i) The test drug and reference material do not differ by more than 30 percent . . ."

"(ii) In at least 70 percent of the subjects, the test drug product is at least 70 percent as bioavailable as the reference material . . ."

Stated somewhat differently, an antipsychotic generic is termed bioequivalent when in 70 percent of the test subjects it falls within plus or minus 30 percent of the innovator drug.

What may be the clinical implications when a severely ill elderly patient is switched from one product to another, if such a wide range of difference is permitted?

The very nature of the mental illnesses treated with phenothiazines mandates the use of bioavailable/bioequivalent drug products. These medically important drugs are typically used in the treatment of schizophrenia, organic psychosis, and the manic phase of manic depressive illness. Such patients are often so disabled by the severity of their illness that they cannot give legal consent. Because of the nature of these disorders, toxic effects or lack of efficacy that may be associated with the use of bioinequivalent phenothiazine drug products may go unrecognized by the physician. The 1979 Final Task Force Report of the American College of Neuropsychopharmacology (ACNP) points out that "often any aberration in clinical symptoms is ascribed to the idiosyncracies of the patient and rarely ascribed to differences in drug products." It was the Task Force's opinion that bioavailability/bioequivalence and pharmacokinetics should be of major importance in the clinical use of psychotropics should be out because of the nature of the patient population, the need for chronic use of such drugs, and the extensive metabolism of psychotropic agents.

Clearly, one should hesitate and give careful consideration whether a patient particularly an elderly patient (elderly females, in particular, are much more at risk to the side effects of phenothiazines which could be increased when a stronger but still equivalent product is used) should be "switched" from one product to another even from one generic to another.

A similar potential problem exists with loop diuretics, particularly furosemide. In this instance, the generic may differ from the innovator drug by as much as plus or minus 20 percent. A 40 mg tablet, therefore, may have the clinically effect of a 32 mg tablet or a 48 mg tablet. By itself, that range in potency may be unacceptable in certain elderly. However, when an elderly patient is also maintained on digoxin (one of the top nine drugs used for those 85 years and older, as are many diuretics) and lithium (in which the blood level is critical in the very old), careful consideration again must be allowed before substitution is agreed upon.

A Proposal

It is most difficult to collect clinically valid data on these potential problems. First, scientific proof, of course, would demand that a patient, maintained satisfactorily on the innovator furosemide and switched, exhibits worsening of control. (This worsening is easily ascribed to a worsening of the disease). Secondly, control must be re-established by counter-switching, and finally there must be rechallenge. This is, obviously not going to take place. Clinical proof, as already outlined, is often difficult since loss of control and worsening of disease state most often present in a similar manner.

Thus, a different system ought to be applied. This system would revolve around the recognition that there are critical patients, critical diseases, and critical drugs for which generic substitution should never be mandated.

(i) Critical Patients:

Those 75 years and older

Females

Living Alone

With Multiple Pathology and on Multiple Drug Regimens

(ii) Critical Diseases:

Those diseases which are hard to stabilize and in which it has been shown that concurrent drug therapy can be a de-stabilizing factor, such as depression, asthma, CHF, diabetes, other cardiac problems, and psychoses.

(iii) Critical Drugs:

In view of the wide range allowed for "equivalency", the antipsychotics and the loop diuretics would be the first drugs so designated.

It is further proposed that the consultant pharmacist following long-term care patients either in nursing homes or in home care also be extended the professional privilege to reject generic substitution if that seems indicated.

The pharmacist is proposed as an additional safety measure since the role of the consultant pharmacist, created by the federal government in 1974, has been found to be effective, both from an economic as well as a clinical point of view, by the Comptroller General. With the increasing number of elderly, both older and more seriously ill than the "normal" community-living elderly, in home care, the pharmacist may well be the one health care professional most closely familiar with an elder's reaction to drugs.

Summary

Increased cost-containment measures in health care are necessary and must be expected. It remains for health care professionals to indicate those areas where patients, particularly the very old, may be at risk if certain cost-containment measures are initiated.

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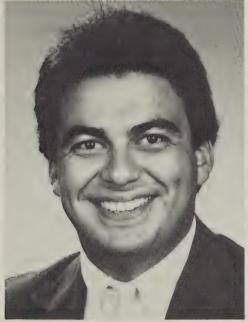
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Eli Lilly and Company Indianapolis, Indiana 46285 ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN REFINEMENT, PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE", ETC.), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.



Pharmacy students, (from left,) Jacqueline Tulachka, Duquesne University; Charles Hoppes and Gerard Ewancio, University of Maryland, and Monica Tarver, Howard University, visit West Virginia University School of Pharmacy museum during the sixth annual Pharmacy Undergraduate Research Seminar Oct. 31 in Morgantown. Students from 11 schools presented papers at the program which was sponsored by WVU School of Pharmacy and Mylan Pharmaceuticals.



Christopher Perez has been named a Syntex professional medical representative. Perez will provide health care professionals in the Prince George's Co., Md. area with medical background and usage information on Syntex pharmaceutical products.



Loewy Drug Company, Baltimore, Md., was selected to receive Syntex Laboratories' 1984 Regional Wholesaler of the Year Award for the Mason-Dixon region. Joseph M. Meyerowitz, (left), Loewy sales manager, and Benjamin S. Mulitz (right), Lowey president, receive the award from Robert J. Hoerdeman, Syntex regional manager.



Kevin J. Fortier has been assigned to the Cumberland territory for The Upjohn Company. He recently completed initial training at The Upjohn Company Learning Center in Kalamazoo, Michigan. Kevin is a graduate of James Madison University.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

CHLORAMPHENICOL:

Chloramphenicol (Chloromycetin) is a useful antibiotic in treating invasive Salmonella, H. influenzae—Type B, meningitis, anaerobic infections, and rickettsial diseases. When changing routes of administration from intravenous to oral, no adjustment in dose is needed. However, individual variation does remain and plasma levels would be evaluated to insure that concentrations of the antibiotic remain between 5 to 25 mg/L. *J Clin Pharmacol*, Vol. 24, #4, p. 181, 1984.

POST/MENOPAUSAL ESTROGEN USE:

The use of estrogen-containing oral contraceptives has been associated with an increase in the incidence of breast cancer. The same association has been said to be true of postmenopausal estrogen use, but a recent study involving over 3000 women has suggested that there is little or no risk of breast cancer associated with the use of estrogen after the menopause. Although the question may never be fully answered to the satisfaction of all, some physicians feel that when menopausal symptoms or osteoporosis become severe, the risk of breast cancer is offset by the benefit of estrogen therapy. *JAMA*, Vol. 252, #1, p. 63, p. 81, 1984.

SMOKING AND COUGHING:

A survey of over 15,000 children, aged 8 years thru 19 years, has yielded some interesting statistics dealing with the effect of smoking by parents and the incidence of coughing in their children. The authors have concluded that a definite link between smoking in the home and coughs in children is present. This may not only proudce immediate complications but may make the child more susceptible to problems in the future. *Br Med J*, Vol. 288, #6431, p. 1647, 1984.

ALUMINUM TOXICITY:

Patients with renal failure accumulate aluminum ions in the plasma which can be deposited in bone tissue and subsequently lead to osteoporosis. Deferoxamine (Desferal) is an agent used to treat iron toxicity, but recently it has been shown to be beneficial in removing aluminum in these renal compromised patients. The drug is used intravenously because it is not absorbed when given by the oral route. *N Engl J Med*, Vol. 311, #3, p. 140, 1984.

RECURRENT HERPES:

Fifty-six patients with recurrent genital herpes infections were treated with either acyclovir (Zovirax) 200 mg, four times daily or a placebo for 12 weeks. The drug was effective in preventing redevelopment of symptoms and further studies will be designed to determine if the beneficial effect will be seen at lower drug doses. *Lancet*, Vol. II, #8394, p. 57, 1984.

ETHANOL AND HEPATOTOXICITY:

Large doses of ethanol taken chronically can lead to hepatic destruction presumably by reducing glutethione concentrations in the liver which act to protect the hepatic cells from damage. Initial hypotheses suggested that oxidative stress produced by the alcohol increased the catabolism of glutethione. The authors of this article speculate that the hepatotoxicity is actually due to an alcohol-induced suppression in the synthesis of glutethione. This increases the risk of hepatoxicity when the organ is subjected to hepatotoxins such as acetaminophen. *J Pharmacol Exp Ther*, Vol. 230, #1, p. 7, 1984.

MOTION SICKNESS:

Volunteers were given either meclizine, transdermal scopolamine, or a placebo and then subjected to a machine designed to mimic motions which are capable of producing motion sickness. The transdermal scopolamine proved to be more effective than both the meclizine and placebo. *Clin Pharmacol Ther*, Vol. 36, #1, p. 116, 1984.

RENAL FUNCTION:

The control of renal plasma flow is at least partially dependent on prostaglandin-induced vasodilation of renal arterioles. Aspirin and most non-steroidal anti-inflammatory drugs have been found to further reduce renal flow in some patients with already compromised function. Sulindac (Clinoril) has been noted to produce little, if any, effect on renal flow so investigators designed an experiment to determine the mechanism responsible for this phenomenon. The authors have concluded that since sulindac is a pro-drug and has to be converted to the sulfide for activity, renal tissue may be spared its antiprostaglandin effect by utilizing renal enzymes to re-convert the active drug back to its inactive sulfoxide. *Clin Pharmacol Ther*, Vol. 36, #1, p. 85, 1984.

POISONING WITH ASPIRIN:

Aspirin was a common cause of toxicity in children under the age of five years, but after the introduction of the safety cap, the incidence of aspirin in this group of people was significantly reduced. Therapeutic mishaps still account for 25% of all poisoning by medication and the incidence of non-salicylate induced toxicities has increased. *Clin Toxicol*, Vol. 21, #3, p. 321, 1984.

LUNG CANCER:

The risk of lung cancer increases with the use of cigarettes, but a change from a nonfilter to a filter and/or a reduction in the number of cigarettes smoked per day will reduce the likelihood of lung cancer. Cessation of smoking reduced the risk most dramatically. *Br Mea J*, Vol. 288, p. 1953, 1984.

Pharmacy, Home Care and the Elderly

A Resolution Submitted By

Peter P. Lamy, Ph.D.

Director, The Center for the Study of Pharmacy
and Therapeutics for the Elderly
School of Pharmacy
University of Maryland at Baltimore

The Home Health Care Committee Maryland Pharmaceutical Association Madeline Feinberg, Pharm B.S. Chairperson

Submitted to the A.Ph.A. House of Delegates

PREAMBLE

The Home Health Care sector is growing rapidly, Drugs often provide the major modality of chronic disease management for an increasing number of elderly patients with mutiple pathology. It is vitally important that it be recognized that consultant pharmacist services must be provided to these patients, as they are provided now, under Federal mandate, to federally-financed patients in skilled nursing facilities. Consultant pharmacist services in long-term care have been found effective in both clinical and economic terms. They are needed in long-term care in the home but they must be adequately reimbursed.

- WHEREAS the number of elderly is growing rapidly in the United States, and
- WHEREAS the number of elderly, now 11.6% of the population, will grow to approximately 20% by the year 2,000 and
- WHEREAS the aging population itself is aging, those over 85 years of age projected to increase by 120% by the year 2000, constituting an increase in 1.4 million, and
- WHEREAS the total population of elderly in need of longterm care is expected to increase between 7.5 and 9 million by 1990, and
- WHEREAS under the current system of long-term care, nursing home care is for many elderly the only available care service for health care, as well as personal care, and
- WHEREAS it is anticipated that the population in need of nursing home medical and health care will double in the next 20 years, and
- WHEREAS the number of nursing home beds for elderly, now about 1.24 million, will need to be increased to approximately 2.8 million, and
- WHEREAS the current increase (by percent) in new nursing home beds indicates that this needed and/or desired number will not be achieved at the current rate of growth, and
- WHEREAS the current system of prospective payment will make it likely that more and more seriously ill elderly will be in need of alternate care systems, and
- WHEREAS the Secretary of HHS has been directed to institute the DRG system for Nursing Homes, and

WHEREAS it is likely that nursing homes may soon have to provide care for long-term care patients such as alcoholics and mental patients, thus reducing the number of beds available to the elderly, and

WHEREAS Home Care is the most rapidly-developing alternate care system even for frail, seriously ill elderly, and

WHEREAS Pharmacy and pharmacists have already developed valuable services for the Home Care patient,

NOW, THEREFORE

BE IT

RESOLVED that the American Pharmaceutical Association expend all efforts to immediately establish a Pharmacy Consultant Role for Home Care and be it further

RESOLVED that this role parallel the role of the consultant pharmacist mandated by the Federal Government for all federally-financed patients in skilled nursing facilities, a role found effective both in economic terms and clinical terms by the Comptroller General, and be it further

RESOLVED that the mandated role for the pharmacist be expanded to include medication record review in nontraditional areas such as the office of the County Commissioner of Health, and be it further

RESOLVED that the American Pharmaceutical Association expend all efforts that Medicaid and other third-party payors recognize this vital role of the pharmacist in reducing the hazard of drugs and maximizing their therapeutic effectiveness by reaching agreement for fair and equitable reimbursement for consulting functions which is not tied to the provision of medications, and be it further

RESOLVED that consultant pharmacists in home care be charged with advice on nutrition-drug interaction, as the Joint Commission on Accreditation of Hospitals now demands in acute care hospitals, and be it further

RESOLVED that the American Pharmaceutical Association negotiate strongly with Medicaid and other third party payors that pharmacists be reimbursed for innovative packaging that will minimize drug defaulting, increase the opportunity for audit and drug use review and meet better the informational needs of the elderly and the caregiver.

JANUARY, 1985 29

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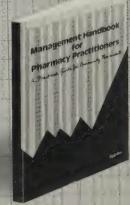
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Preference will be given to candidates having formal training, post graduate instruction and experience in association management or administration.

Qualified candidates should submit resume, references and present compensation, no later than March 15, 1985. All information submitted will be treated in a confidential manner consistent with the requirements of the search process.

Required information should be mailed to Patrick Collins, Pharmacist, Chairman Search Committee, % Wisconsin Pharmaceutical Association, 202 Price Place, Madison, WI 53705.



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February, 1985 VOL. 61 NO. 2



OTC Foot Care Products

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- Thomas A. Grand

The Rural Community Pharmacist

- Madeine Families - Edward Amadla

The Elderly: Why Concern

- Peter P. Lamo

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Answer to December's Puzzle

The hidden words are:

	Word	Row	Col	Direction
1.	ACETAZOLAMIDE	34	14	Right to Left (West)
2.	ALDACTAZIDE	32	12	Right to Left (West)
3.	ANHYDRON	10	13	Diagonal (Northeast)
4.	BENZTHIAZIDE	21	13	Diagonal (Southwest)
5.	CHLOROTHIAZIDE	14	15	Right to Left (West)
6.	CHLORTHALIDONE	11	4	Left to Right (East)
7.	DARANIDE	23	12	Diagonal (Northwest)
8.	DIAMOX	24	5	Diagonal (Southeast)
9.	DIURIL	18	11	Right to Left (West)
10.	DYAZIDE	28	11	Diagonal (Northwest)
11.	ENDURON	24	14	Diagonal (Southwest)
12.	ESIDREX	16	10	Right to Left (West)
13.	FLUMETHAZIDE	15	14	Right to Left (West)
14.	FUROSEMIDE	12	4	Left to Right (East)
15.	HYDRODIURIL	13	12	Right to Left (West)
16.	HYDROMOX	18	12	Diagonal (Southwest)
17.	HYGROTON	20	12	Diagonal (Southwest)
18.	LASIX	15	13	Top to Bottom (South)
19.	METHYCLOTHIAZIDE	35	16	Right to Left (West)
20.	NAQUA	30	15	Right to Left (West)
21.	NATURETIN	17	4	Diagonal (Southeast)
22.	ORETIC	7	15	Diagonal (Northeast)
23.	POLYTHIAZIDE	31	5	Left to Right (East)
24.	RENESE	24	4	Diagonal (Northeast)
25.	SPIRONOLACTONE	33	15	Right to Left (West)
26.	TRIAMTERENE	21	6	Diagonal (Southeast)

Ronald A. Sanford, P.D., President

SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. I, NO. 12

Advising Consumers on OTC Foot Care Products

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Cincinnati, Ohio

and

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Goals

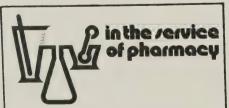
The goals of this lesson are to:

- discuss the etiology and treatment of minor self-treatable disorders of the feet and toenails;
- review the pharmacology and therapeutics of OTC remedies for these disorders.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. choose the appropriate OTC



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agent for treating minor disorders of the feet and toenails;

- 2. explain the proper technique for applying these OTC agents;
- 3. know when to refer the consumer to a specialist when selftreatment is not appropriate.

Introduction

This lesson reviews relevant information on OTC foot care products. This includes corn and callus removers and ingrown toenail relief remedies. The related subject of nailbiting and thumbsucking deterrents is also discussed. While none of the conditions considered in this lesson causes serious pathology, each is commonplace. Also, the conditions may induce intense pain or cause needless embarrassment if allowed to go untreated. Another common affliction of the foot and nails, athlete's foot, was discussed in a previous lesson, "Self-Medication of Topical Fungal Infections."

What Are Corns and Calluses?

The cells that comprise the outermost layer of skin (i.e., stratum corneum) are generally replaced by a new layer of cells approximately once a month. The precise mechanism for this occurrence is dependent on the innermost layer of epidermal tissue that is constantly undergoing cell reproduction (mitotic division). These newly formed cells migrate from the lower levels, through the upper layers of skin, onward to the skin's surface at a rate that is approximately equal to the rate of shedding of the older cells on the surface.

Whenever there is constant pressure or friction against the skin, this rate of shedding increases. This leads to a faster cell reproduction rate at the innermost layer. This in

turn, then, causes the stratum cornum to thicken, resulting in accumulations called corns and calluse Once the friction or pressure is relieved, the cell's mitotic division rais reduced. This results in eventual disappearance of the corn or callutissue.

While both of these thickens growths of skin (hyperkeratoses) a similar in many ways, there are son

differentiating factors.

As stated, both corns and callus are abnormally thick areas of sk tissue. Both are caused by prolong exposures to pressure or fricting against the skin, and both can painful. In time, both will disappe when the friction or pressure is a lieved, and the cell reproduction returns to normal.

The major difference betwe corns and calluses is that corns ha central cores with defined borders thickened skin surrounding the and calluses do not. A callus has indefinite border edge that m range from several millimeters several centimeters in diameter. Bo are raised areas of tissue. Corns normally yellowish-grey in col their central cores are pointed ward. This presses against ne endings in the skin to cause pa Calluses most often have the same slightly lighter coloration as norr skin, and they retain the usual I tern of skin ridges on their surface Corns are more common on the or edge of the little toe. Calluses n form anywhere.

Corns invariably form over a beprominence, adding to their pain ness since there is less flexibing when additional pressure is applicalluses form on weight-bearing as and may be located on the scovering the joints in the feet hands. Since they are usually for to protect underlying tissue from to overly uncomfortable.

is reason, there is some question as whether calluses should be reved. If they are, it should be done the extreme caution since, in realian naturally developed protective echanism is being removed. If the llus is cosmetically or psychologilly disturbing to the individual, it far better to remove its cause than remove the callus.

The same concept is somewhat the for corns. Since corns usually sult from ill-fitting shoes, the use must be corrected or corns will variably return. Shoes that are too that or cause crowding of the toes ust be replaced. Or it may be a light seam or support within the pethat is the cause. Such condinus may be readily corrected by a perepairman.

There is always the possibility that affliction is actually a wart, cyst, tumor. These disorders must be ed out before self-medication is

dertaken.

The FDA advisory panel that rewed OTC corn and callus relievdifferentiated corns into five catpries: hard, soft, "O-corns", seed, d neurovascular corns (Table 1). e panel recommended that only rd corns should be considered to self-treatable. Medical supervin is required for removal of the ner four types.

TABLE 1 Types of Corns

Hard Corns: shiny and polished; occur on surface of toe joints; the most common form of corns.

Soft Corns: whitish; occur in the webs between the fourth and fifth toe; continually macerated due to sweat accumulation.

'O' Corns: hard rimmed but soft center; intermediate between soft and hard; occur anywhere around toes, usually very painful.

Seed Corns: tiny and compact; usually found with calluses on the sole of the foot; usually asymptomatic.

Neurovascular Corns: contain blood at the core and occasionally bleed; usually found on the side of the foot near the great toe; must be surgically removed since they don't respond to OTC treatment. Bunions. Another type of foot problem, the bunion, is a swelling of one of the hollow chambers (bursa, pl:bursae) located around most bone joints. Although bursae are located throughout the body, only those of the foot are associated with bunions. The function of these bursae is to provide flexibility and some elasticity to the tissues surrounding the skeleton and its joints to allow for body movements.

The bursae, along with the great toe and the inner side of the foot, give the foot the mobility we need to walk. However, if there is a skeletal abnormality that causes an outward deviation of the great toe leading to prolonged pressure on the adjacent bursa, inflammation becomes covered by extensive overgrowth of keratin tissue, i.e., the bunion.

Bunions are invariably caused by improperly fitted shoes or abnormal foot structure. They may also result from improper stance or alteration in walking patterns. The advice of an orthopedist or podiatrist is necessary to assure safe and effective treatment. Hopefully, bunions will be asymptomatic with properly fitted shoes, protective pads, or corrections in stance, but they can become swollen, tender, and painful. In some instances, surgical correction is needed.

We will not discuss bunions further in this lesson because there is currently no evidence that any OTC agent effectively treats them, other than providing mild relief of pain.

Treatment of Corns and Calluses

The medical treatment of a corn or callus will be unsuccessful unless its cause is discovered and eliminated. If the problem is due to ill-fitting shoes or hosiery, footwear must be carefully selected so that it is non-binding and distributes body weight evenly over the entire foot. If a corn or callus is caused by anatomical malformation, surgery may be required. In any instance, the goal is to alleviate the pressure and friction that is causing the excessive stratum corneum growth.

Since corns and calluses result from hyperkeratinous growth, topical treatment with keratolytic agents is beneficial. Several substances have been advocated through the years including salicylic acid, phenoxyacetic acid, and zinc chloride. Salicylic acid has demonstrated the greatest success rate. When it is properly used, it is also safe.

The effectiveness of salicylic acid as a corn/callus remover results from its keratolytic action. It loosens cells in the epidermis permitting their easy removal. The exact mechanism for this effect is not known, but it is postulated to result from lowering the pH of the area. This causes the epithelial cells to hydrate from accumulation of endogenous fluid; the cells then swell, soften, and shed.

Since moisture is essential for salicylic acid to work, it is beneficial to apply the acid to corns and calluses and then apply an occlusive cover. This can be accomplished with flexible collodion or a medicated disk, pad, or plaster (see Table 2 for the "official" definitions of these items). All of these measures will prevent moisture evaporation, assure contact of the medication to the affected area, and facilitate penetration of the active ingredients into the corn or callus. Soaking the foot in warm water for 15 to 30 minutes prior to application of salicylic acid also aids its keratolytic activity.

While salicylic acid is keratolytic in strengths as low as 3% (i.e., as in anti-acne remedies), the FDA OTC advisory panel has concluded that the proper concentrations for treating corns and calluses are 12 to 40% in medicated disks, pads, or plasters, and 12 to 17.6% in collodion vehicles.

When recommending salicylic acid as a topically-applied solution in flexible collodion or impregnated into various commercially available medicated products, pharmacists should counsel patients on several important points.

Since the vehicle for collodion-based products is extremely volatile, the container must be kept tightly sealed between each use, and stored away from heat or flame. While safe for topical use, salicylic acid in collodion can be toxic when ingested. Thus, it should be kept out of the reach of children. To assure that salicylic acid does not damage healthy tissues, petroleum jelly (e.g., Vase-

TABLE 2 Definitions of Medicated Corn Remedies*

- 1. Medicated Disk. A topical medication, usually incorporated in a skin-contact adhesive base, carried on a fabric, plastic, or other suitable backing cut to the size and shape of the lesion to be treated.
- 2. Medicated Pad. A topical medication consisting of an appropriately-sized protective pad of fabric, plastic, or other suitable cushioning material in or on which the medication is carried.
- Medicated Plaster. A topical medication, usually incorporated in a skin-contact adhesive base, spread upon a fabric, plastic, or other suitable backing.
- *As published by the FDA Advisory Panel on OTC Corn and Callus Removers.

line™) can be applied around the corn or callus prior to application to keep the acid from destroying surrounding skin. Consumers should also be advised to carefully read, understand, and follow all label directions.

Diabetics, because of circulation deficiencies, should obtain medical advice before initiating self-treatment with any OTC corn/callus reliever. Any person noticing excessive irritation, bleeding, infection, pus formation, or discomfort at the site of application should contact a physician before proceeding with unsupervised treatment.

Complete removal of all corn and callus tissue is not necessary to alleviate pain and discomfort. Therefore, when using an OTC salicylic acidimpregnated disk or plaster, application should be restricted to five treatments lasting over a period of 14 days or less. Prolonged use affords little extra benefit, and adds to potential toxicity problems. Table 3 lists the directions and warnings that the FDA panel has suggested for corn/callus relievers.

Phenoxyacetic Acid and Zinc Chloride. The review panel also reported that phenoxyacetic acid (phenoxyethanoic acid) and zinc chloride are safe for topical OTC use,

TABLE 3 Proposed Labeling for OTC Corn and Callus Removers

A. DIRECTIONS:

- 1. For active ingredients formulated in a collodion vehicle. "Cleanse feet thoroughly with soap. Soak in warm water for 15 to 30 minutes and dry feet thoroughly. Circle corn or callus with a ring of petrolatum to protect surrounding skin. Apply product one drop at a time to sufficiently cover each hard corn or callus; let dry. Repeat this procedure daily until the corn or callus is removed or partially removed to provide comfort. Do not use medication for more than 14 days."
- 2. For active ingredients formulated in a pad, plaster, or disk dosage form. "Cleanse feet thoroughly with soap. Soak in warm water for 15 to 30 minutes and dry feet thoroughly. Cut pad, plaster, or disk exactly to cover the corn or callus. Apply the pad, plaster, or disk. Remove pad, plaster, or disk. Remove pad, plaster, or disk after 48 hours and soak feet for 15 to 30 minutes. If the corn or callus is not soft enough to be removed, repeat the procedure. Do not exceed five treatments over a 14-day period."

B. WARNINGS:

- "Do not use this product if you are a diabetic or have poor blood circulation because serious complications may result."
- "Do not use on irritated skin or on any area that is infected or reddened."
- 3. "If discomfort persists, see your doctor."
- 4. "Care should be used to avoid contact of product with the skin surrounding corn or callus."
- 5. "Do not use this product on soft corns."
- 6. For any products containing collodion:
 - a. "Highly flammable, keep away from fire or flame."
 - b. "Store at room temperature away from heat."
 - c. "Keep bottle tightly capped."
 - d. "Avoid inhaling vapors."
 - e. "If product gets into eyes, flush with water to remove film and continue to flush with water for 15 more minutes."

but there is insufficient evidence to demonstrate their effectiveness for removing corns or calluses. The results of only two studies were available to the panel. While both studies claimed effectiveness for phenoxyacetic acid, there were some flaws (in the panel's opinion) in the experimental protocols. For example, the study submitted by the phenoxyace tic acid sponsor showed satisfactory results, but the panel felt that these results were open to question. It re ported that the effectiveness of the product depended on the dexterity of the individual who removed the corn after treatment, the vigor with which the individual performed the task, and the subjective decision o the observer in deciding whether o not the core of the corn had been re moved. What this basically means i that the manufacturers of corn reme dies containing phenoxyacetic acie must perform additional studies to prove that this agent is effective without regard to any subjective contributing factors.

Zinc chloride was also ruled saf since it has been used for many year as a topical astringent, antibacteria antiperspirant, and tooth desensitizer. Interestingly, it is not promoted a single entity corn/callus relieve but instead has been included as a active ingredient usually in comb nation with salicylic acid. To contirue its marketing as an active ingredent, manufacturers must prove the zinc chloride adds to the action as an active ingredient must cease.

Other agents were also reviewe by the panel and found to be either unsafe or ineffective for this indication (see Table 4).

Ingrown Toenails

Toenails protect the softer tissue the ends of the toes. However, if the nail curves into the corner of the total and becomes embedded in the surounding soft tissue, pain and if flammation often occur. Untreate the condition can progress to ulcertion, widespread inflammation granulation tissue (large masses tissue formation), infection, are even septicemia (blood poisoning)

In actuality, the term "ingrow toenail (onychocryptosis) is not a solutely correct to define the actuality to the correct to define the actual term."

TABLE 4 Substances Proposed to be Banned as OTC Corn and Callus Reliever Active Ingredients

Allantoin
Ascorbic acid
Belladonna
Chlorobutanol
Diperodon
Glacial acetic acid
Ichthammol
Iodine
Methylbenzethonium chloride
Methyl salicylate
Pantothenol
Phenyl salicylate
Vitamin A

offliction. The nails do not "grow" nto the toe. Instead, they become embedded in the tissue.

The best method for treating inrown toenails is to avoid the most common cause, i.e., improper trimning. The correct method of trimning the nails is to cut them straight cross without tapering the corner in ny way (Figure 1).

Another causative factor is tight losiery or shoes which force the latral edge of the nail into the toe correr by direct pressure. Even tight bed overs on a bed-ridden person can ause ingrown toenails. Fungus inections can thicken the nails so they evelop rough edges which are drivn into the softer tissues as the indiidual walks. Ingrown toenails can lso be hereditary; some families are fore predisposed to them than others.

Treatment of Ingrown Toenails

The basis for self-treating ingrown toenails is to soften the nail and shrink the soft tissue of the toe in order to provide sufficient room for the nail to grow in its normal position. These effects must be provided until the nail resumes its normal growth pattern on top of the skin.

The FDA advisory panel considered four purported remedies for ingrown toenails: chloroxylenol, sodium sulfide, tannic acid, and urea. It found that there was insufficient evidence to prove that any of these ingredients are safe and effective for such use. The panel ruled, and FDA has agreed, that chloroxylenol and urea are not proper agents for OTC use on ingrown toenails. Therefore, it has been proposed that they be banned from future marketing as ingrown toenail remedies. (Table 5 lists currently available products).

TABLE 5
Ingredients in Representative
OTC Ingrown Toenail Products

Products	Ingredients
Dr. Scholl's Onixol	Sodium sulfide
Nail-A-Caine	Tannic acid
	(benzocaine)
Outgro	Tannic acid

With sodium sulfide and tannic acid, the panel concluded that there is some, but inconclusive evidence, that they are truly effective. It recommended that further studies be un-

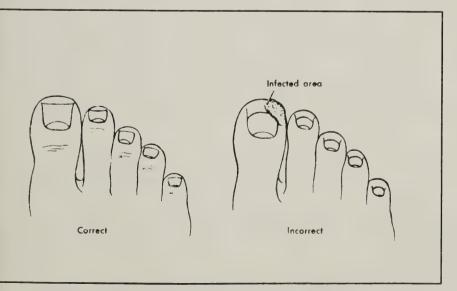


FIGURE 1. Proper nail care, showing the correct (left side) and incorrect (right side) methods for trimming the toenails.

dertaken. In the meantime, these products may continue to be marketed. We will, therefore, briefly review their activity and important patient advice.

Sodium sulfide softens keratin in the toenail as well as that of the skin and surrounding tissue of the toe. This would theoretically provide relief from the pressure and pain caused by the embedded nail. As a side point, nail keratin is very similar to hair keratin; sodium sulfide has been successfully used as a depilatory (it is the major ingredient in many depilatory products) for nearly one hundred years.

Sodium sulfide was not given the official status of "effective" because there were some flaws in its sponsor's study. Without going into complete detail, the exact protocol for double-blind crossover studies was not followed and the results, therefore, were suspect as far as the FDA was concerned. However, it appears once the proper studies are completed, the agent will probably be ruled effective.

Tannic acid, on the other hand, is an astringent. Its proponents claim that when it is applied to the area of the ingrown toenail, tannic acid hardens the skin surrounding the embedded nail. This then allows sufficient room for its normal growth and position.

After reviewing all the data submitted to it, the FDA advisory panel concluded that there is insufficient evidence to show that tannic acid alone is effective in hardening the skin and shrinking the soft tissue surrounding ingrown toenails. It is necessary for controlled studies to be done showing the effect of tannic acid alone on the intact skin and soft tissue surrounding an ingrown toenail.

Patient Advice. Concerning patient advice, the important points are quite similar to those pertaining to corns, especially as they relate to diabetics and other patients with poor circulation.

There is a specific warning against application of these agents to broken skin and open sores because of the possibility of systemic absorption and toxic reactions. The panel also recommended that a warning to consult a doctor if symptoms of in-



Hidden Costs

The direct costs of health care actually account for only 40 percent of the total cost of illness. The remaining 60 percent are indirect costs, such as absenteeism and loss of productivity caused by illness. These are as real economically as the health care expenditures usually associated with illness.

Surprising? Yes. But it should come as no surprise that when the patient gets well faster, both the direct and indirect costs can be reduced.



Eli Lilly and Company Indianapolis, Indiana 46285 ection (i.e., redness or pus formation) are present because infections re not self-treatable.

The best method for applying agrown toenail remedies is to first leanse the area thoroughly. A small iece of cotton should then be laced in the affected nail groove. he cotton pledget should be saturated with the medication several mes a day until nail discomfort is elieved. Ideally, the cotton should be replaced once a day. If there is no approvement after one week, the paent should contact a physician.

ail-Related Problems

Another group of OTC's that is sed for "nail-related" problems on e hands is nail-biting and thumb-

icking deterrents.

It is felt that both of these activities e related to habit rather than some grained physiopathological disrbance of the involved person. It afflictions are also reported to quite common. Various studies low that nail-biting occurs in over 10% of children; nearly 50% of innts suck their thumbs. The habits minish as the individuals age. It also adults bite their nails in thumbsucking generally stops ontaneously around age four.

Nail-biting is related more to nervisness than is thumbsucking, hich is considered to be a meaningis, yet natural, habit in newborns. any experts believe the act begins fore birth and that thumb and finr suckers are not emotionally dis-

rbed in any way.

Even though both are common and ually non-pathogenic, either can id to problems if they are done exsively. In some cases, the nail is ten back so far that the nail plate parates from the underlying tissue. severe cases, they are bitten back the point that the nail bed bulges

beyond the nail plate, so inflammation and hyperkeratosis result. In either instance, open wounds can form making the fingertips quite susceptible to infections.

While it has been stated that nailbiting is more a habit than a pathological condition, there are some psychological factors involved. Absolute proof is lacking at this time, but there is good evidence that in some individuals nail-biting is a normal response to emotional stress, discomfort, psychological pressure, or maladjustment. In others, it is merely a means of providing oral gratification.

Several different types of treatment have been used to overcome nail-biting. It is relatively clear that the individual must be motivated to stop. A prime reason is the cosmetic embarrassment of unsightly and jagged nails. Oftentimes merely reminding oneself of the unconscious habit is enough.

One way to successfully accomplish this is to apply a disagreeable tasting substance on the nails so that as soon as it touches the mouth and tongue, the sensation is repulsive enough to discontinue the practice. This is the premise for use of OTC nail-biting and thumbsucking deterrents.

As with nail-biting, if thumbsucking is excessive or extends beyond infancy, serious clinical problems can occur. Most of them relate to improper mouth and tooth formation. They include incomplete eruption of incisors, improper palate formation, crossbite, and malocclusion (improper bite). In extreme cases, abnormal respiration, swallowing, and speech have developed as have mouth breathing and deviated septums.

Ingredients. The two ingredients found in OTC nail-biting and thumbsucking deterrents are denatonium benzoate and sucrose octa-acetate. Don't let the "sucrose" portion of the name fool you. This substance, as well as the former one, imparts a very bitter taste. In fact, they are both the basis for denaturing alcohol, to make it unfit to drink.

The panel that reviewed them concluded that they are both safe for use as nail-biting and thumbsucking deterrents, and there is some evidence that they are effective. As is so often the case, however, controlled studies will be needed before either substance will be placed in the official "safe and effective" category. Until that time, they are listed in Category III.

The panel has recommended that, should they eventually be proven by adequate testing to be effective (all appearances are that they will be), their labeling should advise that they be used by persons aged four years and older. The panel was convinced that there is no need to deter thumbsucking in children under four. Other appropriate warnings include avoiding contact with the eyes, and if they contain prescription-grade shellac, "keeping them tightly closed and away from heat or flame."

Patient Advice. Patient advice is simple. Adults must want to stop biting their nails. If not, the likelihood of success with any OTC product is questionable. With thumbsuckers, most experts agree that up until age four, the problem should be ignored or the child be occasionally reminded to stop. After age four, a decision has to be made whether parental harassment or an OTC deterrent is best. If the thumbsucking deterrent is selected, the proper method is to apply it immediately following hand washing and at bedtime. Consumers should be strongly advised to avoid rubbing their eyes if an OTC product has been applied to the fingers.

This and That About Pharmacy

by Leon Weiner, P. D.

Pharmacy Family—Some babies are born with spoons in their mouths. Not so with Barbara Dorsch Wirth, Pharmacist at Voshell's Pharmacy. Barbara, UofMD Pharmacy 1972, was born with a pharmacy spatula in her mouth and here below are the facts to prove it.

Father—Joseph U. Dorsch, UofMD Pharmacy 1939— Voshell's Pharmacy

Husband—Gary J. Wirth, UofMD Pharmacy 1979—Giant Pharmacy

Father-in-Law—Francis Wirth Jr., UofMD Pharmacy 1952—Good Samaritan Hospital

Brother—Joseph U. Dorsch Jr., UofMD Pharmacy 1978—Voshell's Pharmacy

Sister—Margaret V. Dorsch, UofMD Pharmacy 1976— McDougall's Pharmacy

Husband's Step-Sister—Sherry L. Williams, UofMD Pharmacy 1976—Pharmacy in New Mexico

Incidentally, both Gary's mother and Barbara's mother are school teachers. No, it is not true that you have to be a pill to belong in their family, but it sure wouldn't hurt.

Bob Welsh, UofMD Pharmacy 1955, was born in Cumberland, MD, but came to live in Baltimore at a very young age. Two very important event occurred in Bob's life there. He attended and graduated Pharmacy School and he married the former Jane Erdman. Bob worked in the Baltimore area for several years before moving to Ocean City in May 1963, where he opened Welsh Pharmacy which is now located at 2114 Philadelphia Avenue. At that time, Welsh Pharmacy was 1 of 3 drug stores in Ocean City. Today there is a total of 7 pharmacies and still growing. Jane and Bob have been blessed with 7 children—3 boys and 4 girls, their ages range from 16 to 28. In addition, they have 2 grandchildren, age 2 and 12. When Bob is not working in the pharmacy, he plays racketball four times a week with the young fellows, fishes for all the local salt water variety and goes sailing in the family 19 foot sailboat. In 1978, he caught a 78 pound white marlin 60 miles off of Ocean City and in 1976, he caught a 5 pound bonefish in the Bahamas. He smiles as he calls these his 3 biggest catches. (His wife, of course, is the third). It is a good possibility that Nancy, the youngest daughter, may attend Pharmacy School and keep the business in the family.



Left to right—Gary and Barbara Wirth, Peggy, Jay and Joe Dorsch

As I walked in front of the prescription counter at Bradley Drugs in Bethesda, Maryland, I overheard one woman say to her friend "If he could only act, I would be able to forget Cary Grant."

Yes, she was talking about Stanley F. Smith, the tall, handsome owner of that store. If Stan had wanted to be an actor, he probably could have. However, he settled for being a full time pharmacist and a part time big game hunter. Stan, as a youngster, lived in Winthrop, Massachusetts and graduated from Massachussetts College of Pharmacy in 1965. He worked a few years in pharmacy and in 1969 he left to become a broker for Reynolds Securities. After 2 years, he realized that the grass was not that much greener outside and decided to come back into pharmacy. In 1972, Stan and his partner, Robert Koenig, bought Bradley Drugs, and in a few years they bought several drug stores in the Virginia, Washington, DC area. Dr. Smith's interest in hunting started when he was a stockbroker and he began to go geese hunting at Tangier Island, Maryland. He has hunted in many places from West Virginia to Montana and from Alaska to Africa. Stan's biggest thrill as a hunter came in October 1983 when he shot the largest grizzly bear ever taken out of Alaska. It measured 26³/₄" skull with a 10 foot square of it's cape. Stanley and his wife Kathy, have been married 16 years and are the parents of 11 year old twin boys and an 8 year old girl.

PHARMACY BRIEFS

Brian D. Sweeney, UofMD Pharmacy 1980, has recently been appointed director of pharmacy services at Mount Washington Pediatric Hospital. Previous pharmacy experience includes St. Joseph Hospital and Howard & Morris Pharmacy in Towson.

Alfred Davis, UofMD Pharmacy 1950, is one of the owners of the popular Pimlico Restaurant which moved to a new location just above the beltway on Reisterstown Road.

Douglas Pryor, UofMD Pharmacy 1971, has been appointed assistant administrator, materials management at North Charles General Hospital. Previously, he had been hospital's director of pharmacy.

Joseph F. Zarych, University of Pittsburgh 1952, has been presented a 35 year pin for service at People's Drug Store. For the last 33 years, he has worked at People's #1150, 4670 Suitland Road, Suitland, Maryland.

Gail H. Rosen, UofMD Pharmacy 1980, has been named Clinical Pharmacist at North Arundel Hospital.

University of Maryland Pharmacy Class of 1980

Leon Kirzenbaum was married in November 1984. He works for Rite Aid Drug Store.

Paula P. Jandorf became mother of baby boy in November 1984. She used to work for Revco Drug and is now with Tuxedo Pharmacy.

Stuart Hankin will be getting married February 1985. He works at Lutheran Hospital.

The above 3 pharmacists are all graduates of UofMD Pharmacy 1980. If you have a 1980 yearbook, all can be seen on pages 24–25.

CONGRATULATIONS TO ALL!

Jeanette Pritzker and her children presented a hospitality car to Baltimore General Hospital, in memory of Sherman (Buddy) Pritzker and Melvin Carp. Pritzker, a 1942 UofMD Pharmacy graduate, passed away March 14, 1984. The hospitality cart, maintained by auxiliary volunteers, offers free coffee, tea and cookies for families keeping vigils at the hospital.



Gary Fait and Stan Smith with Largest Grizzly ever taken in Alaska.

Fait, on the left, is the registered guide.

Recent Pharmacy Death—George Josef Stiffman, age 75, passed away November 28, 1984. He was one of the former owners of Charles Street Pharmacy in Baltimore, Maryland.

PHARMACY CHANGES—NOVEMBER 1984

NEW PHARMACIES

People's Drug Store #1408 6000 Radecke Avenue Baltimore, Maryland 21206

Bud's Deep Discount Drug Store & More 4001 6158 Greenbelt Road Greenbelt, Maryland 20770

Kaiser Permanente Landover Pharmacy 8300 Corporate Drive Landover, Maryland 20785

Nichols Pharmacy 1111 Maryland Avenue Hagerstown, Maryland 21740

Shapiro's Pharmacy 1504 Reisterstown Road Pikesville, Maryland 21208

Twin Knolls Pharmacy 2525 Riva Road Annapolis, Maryland 21401

Upper Shore Community Mental Health Center Pharmacy PO Box 229, Scheeler Road Chestertown, Maryland 21623

PHARMACIES CHANGE LOCATION

Super Super Drug 8508 Liberty Road Randallstown, Maryland 21133

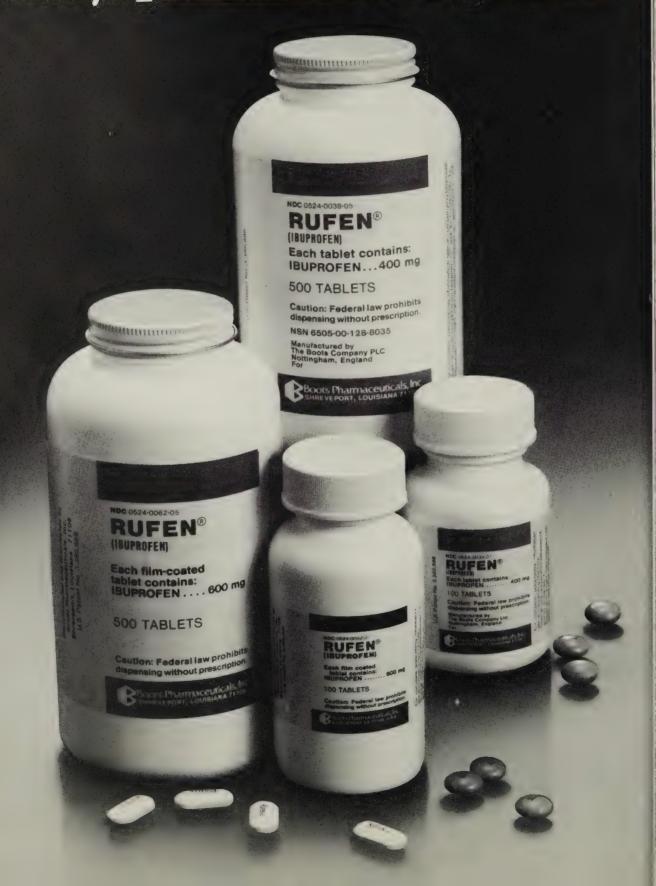
Rite Aid #352 914—18 W. 36th Street Baltimore, Maryland 21211

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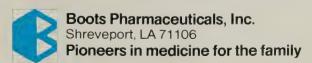
Check with your wholesaler for your exact savings; but here are some typical examples.

Product	Size	A.W.PRufen Direct Cost-Motrin	Savings
RUFEN 600 mg	500	\$ 67.20	\$26.80 (29%)
MOTRIN 600 mg	500	\$ 94.00	
RUFEN 600 mg	100	\$ 15.12	\$ 4.53 (23%)
MOTRIN 600 mg	100	\$ 19.65	
RUFEN 400 mg	500	\$ 48.00	\$18.00 (27%)
MOTRIN 400 mg	500	\$ 66.00	
RUFEN 400 mg	100	\$ 10.80	\$ 3.05 (22%)
MOTRIN 400 mg	100	\$ 13.85	

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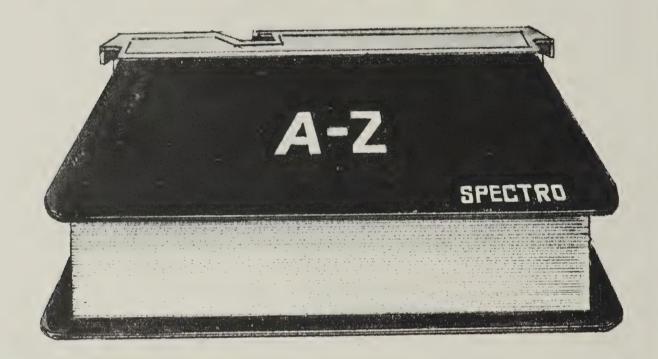
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national scene

High Blood Pressure



Across-the-board reductions in the maximum dosage of diuretics is a prime recommendation of the latest (1984) Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. The committee's previous reports (1977 and 1980) suggested average daily maximums in the range of 100 mg hydrochlorothiazide, 100 mg chlorthalidone, or their equivalents. Based on new data, however, the

committee has dropped its recommended daily dosage to a maximum of 50 mg. The new report also places greater emphasis on the concept of nonpharmacologic therapy—such as weight reduction and sodium restriction. However, use of drugs is generally suggested whenever nonpharmacologic approaches fail to bring the diastolic pressure to 90 mm Hg or lower.

Civil Money Penalties Law



Pharmacists should be aware that the Federal government has a formidable weapon to use in protecting its health care financing programs (Medicaid, Medicare, etc.) from fraud and abuse. The Civil Money Penalties Law allows the government to hit the crooked provider where it hurts the most—in the pocketbook. Under the law, the Department of Health and Human Services can impose a civil money

penalty of up to \$2,000 for each item or service falsely or improperly claimed. In addition, an assessment of up to twice the amount claimed for each item or service can be imposed. HHS says it will not use the law to harass health providers who make honest mistakes, but says it needs the new power to combat an "epidemic" of fraud and abuse.

Direct to Consumer Advertising



Chances continue to be remote that we will be seeing direct to consumer advertising of prescription drugs in the near future. The concept is being pushed by ad agencies, TV networks, and some within the pharmaceutical industry. But strong opposition from health professionals (including pharmacists) and consumer groups, unresolved legal questions regarding liability, and the high

price tag (\$250,000 for a 60-second network TV spot) have combined to slow the bandwagon. Also, both FDA and the Federal Trade Commission claim the right to regulate this type of advertising, so potential advertisers would face a double bureaucratic headache. Before the concept goes any further, FDA will have to issue new regulations to govern actual marketplace testing of the idea.

New DEA Numbers



You will be seeing new Drug Enforcement Administration registration numbers soon. The new numbers, which are being adopted to enable DEA to go "on-line" with its registration system, will begin with a "B" rather than an "A" for practitioners, and a "P" rather than an "R" for manufacturers and distributors. The new

system will also result in the assignment of a lifetime DEA registration number. Both old and new numbers will be in effect over the next two years as DEA switches over to a three-year rather than annual registration cycle. The check digit algorithm used to verify the authenticity of DEA numbers remains unchanged.



The Rural Community Pharmacist: A Trusted Resource For Elders

Madeline Feinberg, Pharmacist

Center for the Study of Pharmacy and Therapeutics for the Elderly, University of Maryland School of Pharmacy

Edward Ansello, Ph.D.

Associate Director, Center on Aging University of Maryland, College Park

Rural pharmacists in certain counties of Maryland will be invited to participate in a unique multidisciplinary professional education program in geropharmacy and gerontology offered by the Center for the Study of Pharmacy and Therapeutics for the Elderly (faculty members: Dr. Peter P. Lamy, Dr. Donald O. Fedder, Ms. Madeline Feinberg) and the University of Maryland Center on Aging, College Park (faculty: Dr. Edward Ansello).

The Andrus Foundation, in funding this project, recognizes that, in general, rural elders are underserved by the health care network, including the social service, educational and recreational systems. It also recognizes on the other hand, that there exists a strong sense of in-place "belonging" among rural elders which discourages outside interference. Rural communities rely on local resources.

In such a setting, the rural community pharmacist becomes a trusted and valued representative of the whole health care system. In fact, the rural community pharmacist bears an enormous responsibility. He (she) must be current on a range of health-related issues, particularly with regard to the older patient. Changes in drug action with age, drug-disease and drug-drug interactions, effects of diet on drug therapy as well as the effect of chronic drug therapy on nutritional status are among several factors which can impinge on the outcome of a particular therapeutic regimen in the older patient. Resources for referral when services need to be complemented, e.g. further medical care, financial or social aid or religious support need to be identified. In addition, the community pharmacist needs to be familiar with preventive care, with mechanical prostehses and the potential adaptation of existing products and services that would aid elderly to maintain the maximum quality of life. The pharmacist needs to be knowlegable about principles of marketing, surveying consumer needs and communication skills. All these, it is believed, will maximize the beneficial impact of the rural pharmacist's services.

While such educational objectives are ambitious,

rural pharmacists are also very busy; often they are overloaded with diverse responsibilities and cannot "get away" to participate in educational programs. Therefore, this project will bring a comprehensive program of research-based geropharmacy education to the rural pharmacist in his/her own community.

The project will target rural or isolated areas with high concentrations of elderly typically underserved by physicians relative to the rest of the state. Three areas are identified: (1) lower Eastern Shore (Dorchester, Wicomico, and Caroline counties), (2) western Maryland (Garret, Washington, Allegheny counties), (3) southern Maryland peninsula (Calvert, Charles, St. Mary's counties). County health department officers and local medical societies will be contacted and their support enlisted. Local aging networks will be consulted and involved in the project. Regional coordinating councils will be established and will include representatives of all involved disciplines to work with project staff. Pharmacists in these areas will be sent an invitation to participate, at no cost. A certificate of participation will be presented at the termination of the program. Eight weekly sessions will be held in locations readily accessible to the participating pharmacists at a time convenient for weekly meetings. Follow-up visits to participating pharmacists will be made periodically to evaluate curriculum content with regard to practice application.

Very briefly, the following topics are planned for the eight weekly sessions:

Week 1—Assessment of physical, social cultural and psychological processes associated with aging and the effects of drug-taking behavior, drug action, and quality of life.

Week 2—Utilization of community resources, including extent, availability and criterial for participation

Week 3—Age-related changes altering drug action, including patient factors, pharmacokinetic and pharmacodynamic changes which may alter drug action; compliance problems.

Week 4—Identification of high-risk patient to prob-

lems with drug therapy, epidemiological and social factors, adverse drug reactions, drugs most likely to cause ADR's.

Week 5-Recent developments in drugs commonly prescribed for the elderly, including NSAIDs, antihypertensives, psychotropics, antibiotics; drug most misused and abused by patient and provider.

Week 6-Acute, chronic and preventive care for elderly; the pharmacist as an information provider for patient and physician and caregiver; DRG's. PPO's, developments in home health care, preventive care.

Week 7-Nutritional needs of elderly, deficiencies induced by diet or drugs, diseases which respond to diet modification, nutritional supplements, drug-nutrient interactions.

Week 8—Marketing to the elderly, consumer behaviors, product, price, distribution and promotion of the pharmacist/pharmacy.

It is anticipated that this project will become a prototype for an expanded regional and national model which addresses the very real needs and concerns of one of American's most essential resources, the rural community pharmacist!

Taxes

Did you know that interest to the IRS has gone up?

For many years, interest due the Internal Revenue Service on unpaid taxes and estimated tax penalties was at the modest rate of six percent per year. Starting during 1981, the rate of interest due the Internal Revenue Service on unpaid taxes and the estimated tax penalty dramatically increased. During 1982, interest rate and estimated tax penalty reached a high of 20% per annum.

Starting in 1983 the rate of interest due the IRS on underpayments of tax will more clearly approximate the current prime rate of interest charged by commercial banks. The rate will change semi-annually on the basis of the average prime rate during the six month period ending on September 30 and March 31. Moreover, interest on underpayments will no longer be simple interest but will be compounded daily, which substantially increases the effective rate of interest over the stated rate.

Greater care is needed in the payment of estimated taxes since understatement of estimated taxes may result in estimated tax penalties at a rate equal to the interest rate. However, unlike interest, penalties are not deductible in determining taxable income. For a taxpayer who is in the 50 percent bracket, the effective cost of the estimated tax penalty is double the interest cost. If the interest rate is 10%, the effective cost of the estimated tax penalty is 20% for a taxpayer in the 50 percent marginal tax bracket.

The rate of interest due the IRS may encourage a taxpayer to pay a deficiency to the IRS to stop the running of interest. A special procedure allows a deposit of tax to stop the running of interest on proposed deficiencies while preserving your right to appeal the proposed deficiency. However, if you are entitled to the return of your deposit the IRS will not pay your interest on the deposit.

Although the same interest rate also applies to refunds, the higher rate will benefit only those taxpayers whose refunds have been delayed beyond 45 days after the due date of the return.

NATIONAL POISON PREVENTION WEEK MARCH 17-23, 1985

Ten years ago, he was the new kid on the block. Today, however, his green scowling face is as familiar to Marylanders as the skull and crossbones he replaced. His name? MR. YUK.® Since 1975, when the Randallstown Jaycees, Blue Cross and Blue Shield of Maryland and University of Maryland School of Pharmacy provided the initial funding to bring this program to the Maryland Poison Center (MPC), over a quarter of a million sheets of MR. YUK stickers have been distributed.

This year, in conjunction with National Poison Prevention Week-85 (NPPW-85), the MPC will again focus on the MR. YUK program. Basically, the MR. YUK symbol has three major objectives: (1) to educate the public about potentially poisonous substances as they identify those items with the Mr. Yuk stickers; (2) to prevent unintentional poisonings by serving as a poison warning symbol to children who have been taught that MR. YUK means NO! Do not touch! and (3) to create an awareness of the name and telephone number of the Maryland Poison Center. The Mr. Yuk symbol is only a tool and must be combined with education and reinforcement in order to be effective.

Pharmacists have played a unique and influential role in poison prevention promotion in Maryland not only with their initial support of the Mr. Yuk program but also with their year-round support of the Maryland Poison Center.

Again this March, we are asking pharmacists to prominently display our poster, "POISON PROOF YOUR HOME" and to distribute other educational materials, such as the "Has Your Child Met Mr. Yuk?" flyer. For more information about our Poison Prevention Week programs, contact Mrs. Annette Hurst on the Maryland Poison Center non-emergency number (301) 528-7604.

An added feature of this year's NPPW-85 activities will be a special poisoning conference for pharmacists sponsored by the Maryland Poison Center and Merck, Sharp & Dohme. This three-hour program will be held on Sunday, March 17, 1985, at the University of Maryland School of Pharmacy and will discuss issues ranging from management of the poisoned patient to drugs of abuse to bites and stings. Additional information is available from Jacquie Lacy or Lisa Booze at (301) 528-7604.

The Elderly: Why Are We Concerned?

by Peter P. Lamy, Ph.D., F.A.G.S.

The 1960s were the decade of Civil Rights. The 1970s were devoted to women's rights. The 1980s are and will be the decade that addresses the rights and needs of the aged. Interest in the problem of aging has grown greatly in the past few years. Strikingly broad and diverse issues have been raised—many of these still needing answers. Myths and prejudices still encrust the subject of aging, and people still disagree as to the nature of problems and how they should be solved. Do we need more or less government action? Do the aged need pity or is pity part of the problem?

But there is movement! That is not only movement through time, but, if one looks closer, one may see perhaps the latest great American reform. One sees a society in the process of permanent reform. The first public commission on aging was founded in Massachusetts in 1909, and now there are literally hundreds, if not thousands of public agencies concerned with the aged. The study of gerontology hardly existed before WW II and again, now there are few universities that have not devoted some part of the curriculum to this subject, although health professional schools still lag far behind.

Voluntary efforts abound, from the Soroptimist Club Denture Effort in Denver to "Repair on Wheels" in New Orleans. There is even a Rent-a-Granny. The American Association of Retired Persons, founded only a quarter of a century ago, has grown to such size that it has received its own zip code.

Perhaps, we can view all of this as quantitative growth of the grey movement—and now we have entered the qualitative growth period. Old age has generally been viewed as a static life stage, defined long ago as life after 60, changed later to 65. Now there are attempts to view old age as part of the continuum of life, part of a dynamic process.

As part of that dynamic process, we look at "bureaucratized aging", a world where choices are made not by the individual but by authorities, as something undesirable, something to which too many elderly have fallen victim.

Concepts have changed, and in old age, family may be less important than friends. And most of all, today older Americans are not objects but agents of reform, and those agents are now looking at the health care system. We as pharmacists must be responsive—and take a leadership role in that reform. And reform is needed.

The number of elderly is increasing. More importantly, the very old, those 85 years and older, are the fastest-growing segment of our population. With increasing age, there are increasing infirmities, disorders, and diseases. Only eight percent of the people who are 65 to 74 years old are functionally impaired, as compared to 18 percent of those 75 years and older (1), and infirmities increase with increasing age even further. According to the Veterans Administration's three stages of life after 65, only very few people 85 years and older can live completely independently. Yet this is the fastest-growing segment of our population. Functional impairment is defined as a person's ability to perform daily tasks-and if the old and very old, or at least a growing number of them, are unable to perform them, then they may also have problems with following a therapeutic regimen.

Among the old, women outnumber men by a ratio of 2:1 or even 3:1 (in institutions), and women are more sensitive to adverse drug reactions than are men. Older women, more so than men, often live alone, and those living alone make more medication errors. Of the six million women living alone, three million live at or near the poverty line. This may mean that they cannot purchase their medications or that they may be undernourished (2).

Undernourishment, in turn, can adversly affect and alter drug action. Indeed, there is ample evidence that many elderly are undernourished, both in institutions and in the community (3). A number of factors can influence the nutritional status of the aged. Poverty is one of those. While the size of the poverty population in the U.S. has shrunk in the last 20 years from more than 22 percent to slightly more than 11 percent, among persons 65 years of age and older, one of every six still lives in poverty (4). Chronic disease can interfere with the nutritional status of a person, and so can chronic drug therapy (5). Older people living in public housing have significantly greater needs than those living in private housing (1).

Drugs are the mainstay of long-term health and medical care. Elderly already account for 79 percent of the antiarthritic drugs dispensed and for 86 percent of all cardiovascular drugs. New and refill prescriptions for

aged living in the community have increased in five years from 14 to 18 per year, and the size of individual prescriptions has also increased. In 1975, chronic prescriptions (drugs taken for longer than two weeks) counted for 57 percent of all drugs dispensed, a percentage that has increased to 69 percent in 1980. Clearly, drugs are becoming more important in the management of chronic diseases.

Yet, we still know very little about drugs and the elderly. The recent medical literature has viewed geriatric drug therapy as complicated, complex, and potentially dangerous. It is still little understood. In some instances (for example the psychotropic drugs), it has been shown that therapeutic failure is often associated with misunderstandings by those who were prescribed these drugs, and misunderstandings most often resulted from poor educational efforts. Perhaps, the provider and the patient "did not speak the same language".

Pharmacy and pharmacists can and must make a major contribution in this field, the field of long-term care and communications. And most importantly of all, we must join the "agents of change", the aged, in their efforts of reform. We can do that by helping to change current attitudes and by helping to re-focus current thinking (Table I).

TABLE I

RE-FOCUS THINKING

FROM

TC

Eternal Youth First 50 years Acute CURE Life Extension Healthy Aging
Second 50 years
Long Term CARE
Compression of Morbidity
Quality of Life
Delay of Dependence

REFERENCES

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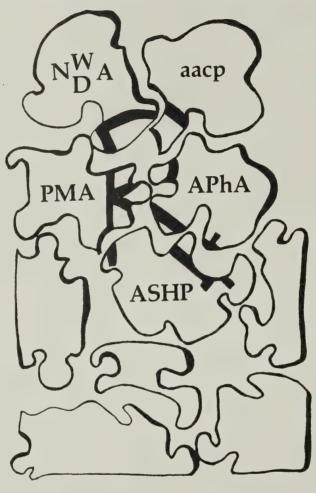
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Things You Should Know FOR YOUR GOOD HEALTH



Managing Stress

For many individuals, the pressures of everyday living can become almost unbearable. Daily we are facing such problems as unemployment, threats to our standard of living, new outbreaks in crime, conflicts with our children and other family members, job pressures, lack of self-confidence, and a long list of other problems.

Stress is defined as a mentally or emotionally disruptive or disquieting influence. Stress is a form of pressure that affects each of our bodies. While a certain amount of pressure appears desirable, the key to healthy living is to be able to manage excessive stress.

Medical researchers tell us that many major illnesses may be either caused or worsened by the effects of stress. The stress associated with emotional reactions to situations seems more important than the stress occurring with physical work and exercise.

In fact, physical activity is often beneficial because it leads to relaxation. Physical stress is, therefore, very different from emotional stress. Experts believe that the following health problems are very closely associated with stress of the emotional type:

- Alcoholism
- Allergies
- Arthritis
- Asthma
- Backaches
- Constipation
- Diarrhea
- Gout
- Headaches
- Heart Disease
- HypertensionMental Illness
- Teeth Grinding
- Ulcers

Excessive stress, if present for an extended period of time, weakens and wears down the body. The ability to resist disease may be impaired greatly.

One of the best ways to avoid stress is to simplify our life-styles. By controlling our wants and desires, it is possible to rechannel our goals and priorities into less stressful situations. Avoiding excess stress can and often must lead to a drastic change in one's value system. Stress avoidance could lead to moving to a different neighborhood, getting a less hectic job, or taking a less exhausting vacation. Some stressful situations cannot be avoided. In such instances, it is usually better to accept a situation and go on living than to worry and become overly anxious.

Some individuals, if not most, have a great deal of difficulty relaxing. Relaxing is essential. Several studies have found that relaxation techniques are effective in reducing high blood pressure. Some of these techniques may include meditation, a hot bath and a few moments rest, or a short afternoon nap for those who have not received adequate rest the previous night. Physical activity is a must. It not only helps ease the frustrations of life, but it releases aggressive feelings and aids in weight loss. Walking, bicycling, swimming, and running are all excellent exercises ... healthful activities that help reduce the effect of stress on the body.

Many of us often feel too tired to exercise. These may often be the very best times to become involved in physical activity. The night's sleep will become more satisfying and stress will be diminished.

State Pharmaceutical Editorial Association

Rx—OTC Switch

Mona L. Gold

There has been considerable attention given in recent months to the "Rx-OTC Switch" question. The debate is not a simple matter of "to switch or not to switch," but presents itself as a complex issue. There are several important points which must be considered before the switch can be answered.

First, there are a number of drugs which are under consideration for the switch, each requiring independent investigation. Second, not all illnesses need the vast extent of knowledge possessed by the physician when determining diagnosis and treatment. Lastly, not all conditions requiring drug therapy need the degree of monitoring that a physician provides. The pharmacist is in a unique position to provide the necessary information that would be required to enable an otherwise prescription

drug product to be switched to OTC status.

The switch process, in general, is good for the public because it can help to lower health care costs by allowing informed self-medication in an easy to access setting. By decreasing the number of doctor visits, both by eliminating unnecessary visits and by decreasing the follow-up visits to get refills on medications to treat chronic or recurrent illnesses, the consumer saves money and time. There would be a concommitant decrease in the number of minor but expensive lab tests performed.1 Costs of the drug products, too can be lowered by the sales increases generated.2

Not only would decreased physician involvement decrease costs, but there may be a benefit in increasing the individual's responsibility for his/her own health care-

better compliance.1

Physicians employed by HMOs would benefit from the switch process when paid on a capitation basis. By decreasing the number of visits per patient, the physician

saves money.3

Patients and some physicians are not the only to benefit from the switch process, however. The pharmacist is able to enhance the role of medication consultant.1 There is also an economic benefit to the pharmacist in that there will be more and better products to recommend to the

public.

One must be careful in too broadly advocating the switch because of the potential negative consequences of unsupervised drug use. Not all drugs need the same level of supervision by the health professional and it is for this reason that a third class of drugs, the "pharmacists legend drug class" should be created. I am not advocating that all drugs switched be included in this class-only those with a potential for improper use, toxicity or severe adverse reactions

The third class is important for these drugs because labeling alone cannot insure proper use of medications, full comprehension by the consumer of the information provided or even that the consumer will read what is pro-

vided.4

An FDA official cautions that critical warning information, e.g. cross allergies with other drugs, may be lost in advertising to the OTC markets. Regarding the Ibuprofen switch, an FDA official, Gary Dykstra actually believes that, "We fully expect there will be some deaths. . ."4

In a recent survey done by American Druggist, 85.6% of pharmacists responding believe that the pharmacist's role as medication consultant should be established by law. Furthermore, 83% favor establishment of a third class

Opponents to the proposed pharmacist legend drug class argue that it has "monopoly overtones" and is being suggested for economic reasons to benefit the pharmacist.2,4 I believe, however, that protection of the public health has far more influence on the third class proponents' stand than economic sway. The pharmacist has a moral and ethical obligation to the public to serve as a health care provider and can do this best when medications with the potential for causing problems when used without medical advice can be dispensed only on a pharmacist's direction.

Other suggested problems regarding the switch, in general, can be countered by establishment of the third class. These include the masking of symptoms and the delay in obtaining medical treatment when necessary,1 problems which would be screened for during pharmacist consultation.

While some opponents have much confidence in the public's ability to properly self-medicate, even believing that the public will be offended by a third class, some drugs still will require some medical intervention which the pharmacist could provide.2,4

AMA reactor, Donald Vidt, MD believes that the switch should be:

'a very coordinated and cooperative effort' on the part of manufacturers, consumers, and health professionals. It's industry's responsibility to avoid negative advertising, the consumer's to be open with health professionals, and the professionals' to cooperate with each other.2

It seems very naive to assume that all parties will be able to cooperate in such a harmonious manner.

A medical viewpoint to the switch was addressed by John Morrissey, MD during a symposium sponsored by the Proprietary Association on November 1, 1982. Doctor Morrissey states that many phsycians rely on placebo effects which won't be as effective when a product could have been obtained as an OTC product and/or is widely advertised to the public. This is evident, he says, because many patients expect to receive a prescription when they visit the doctor and feel cheated when they don't. He believes that many physicians view the switch as a threat, due to the subsequent decrease in number of office visits. This position, he argues, is justified in that many physicians deliberately will not write a prescription to be refilled "p.r.n." so the patient will need to make an extra visit to have the prescription authorized for additional refills when, in many cases, such strict supervision isn't actually necessary.3 In addition, many physicians don't have com-

Mona is a Pharmacy student at the University of Maryland School of Pharmacy and completed this article as part of her course work.

plete knowledge about drugs and there is no guarantee that because a drug has prescription status it will be used

to best advantage.5

Because the public stands to benefit from decreased costs, saved time, and improved access to drugs used for treatment of chronic or recurrent conditions, I believe that the Rx-OTC switch process for certain drugs is a good policy. By including those drugs with potential for problems in a third class, I feel that arguments against the switch can be countered. Most arguments against the third class seem to be centered, not in the name of public health, but in fear of economic losses, i.e., decreased number of doctor visits and lack of availability of the products in non-pharmacist retail outlets. I believe that the third class of drugs enables provision of the benefits of the switch while, at the same time, protecting the public's best interests.

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Pharmacy students appreciated the Kelly Memorial Building as they celebrated the end of the Semester and the beginning of the Holidays with a massive party in the basement

Convention Awards

The Awards Committee of the Maryland Pharmaceutical Association is soliciting nominations from the membership for two prestigious awards which are presented to pharmacists at the Annual Banquet. The Committee decided that more membership input into the Awards process would be appropriate. The two Awards are:

BOWL OF HYGEIA This award is presented annually through the cooperation of the A. H. Robins Co. to a pharmacist who has compiled an impressive record in the area of community service.

MPhA ACHIEVEMENT AWARD This recently instituted award is given to a pharmacist who is distinguished in the area of contributions to the profession of Pharmacy.

Nominations for either of these two awards may be sent to the Awards Committee for consideration. Nominations must be in writing and should outline the qualifications of the individual for the award being considered. Nominations are kept on file each year and may be considered by the Awards Committee in future years. Nominations or inquiries about the nominating process should be sent to the M.Ph.A., 650 W. Lombard Street, Baltimore, Maryland 21201.

Convention Resolutions

The Vice Speaker of the House of Delegates, Elwin Alpern, also serves as Chairman of the Association's Resolutions Committee. The Committee will be meeting soon to consider issues and resolutions for the Annual Convention of the Association, June 23–27, 1985 in Ocean City, Maryland. In order to allow for greater membership participation in the resolution process which forms the basic policy making structure of the Association, the Committee is soliciting input from the membership in the form of suggested resolutions or resolution topics. Resolutions may be sent to the Association at this time with any background or supporting information necessary. They should be sent to the M.Ph.A. Resolutions committee, 650 West Lombard St., Baltimore, Md. 21201.

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The Alumni Association held its Annual Fall meeting on November 11, 1984. Here, Abe Bloom (left) receives the Honorary President's plaque from Alumni Association President Melvin Rubin.



The Baltimore Metropolitan Pharmaceutical Association's Annual Meeting occured at the Pikesville Hilton on November 13, 1984. Charles Spigelmire conducted the traditional introduction of the new BMPA President, Nathaniel Futeral (right) while Board member Larry Hogue observes.



Jack Peters of the E. R. Squibb Company was honored by the BMPA for his many contributions and was named the 1984–85 Honorary President.



The popular BMPA meeting heard presentations from (left to right) Herb Mishel from the new HMO, Health America; Martin Mintz, out-going BMPA President; and Stuart Baltimore, who explained the new Blue Cross-Blue Shield generic drug program.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

EXERCISE AND ENDORPHIN SECRETION:

Exercise is not only becoming a well recognized type of recreation, but is suggested for patients with certain disease states. It has been noted that women who participate in strenuous exercise experience several menstrual abnormalities including delay of menarche, secondary amenorrhea, and inadequate luteal phase. The amenorrhea is mediated at the pituitary level and is probably due to inhibition of the gonadotropin release. This is thought to be mediated by high endorphin levels. To determine the effect of training on women, a group of volunteers were evaluated as to beta-endorphin and met-enkephalin levels prior to participation in an exercise program and then again upon completion of the program. After two months, peak plasma levels of beta endorphin remained high, as they were at the beginning of the training procedure. However, met-enkephalin levels, which were high at the onset, fell to almost control levels by the conclusion of the two month program. It is suggested that both opiods participate in the bodies adaptation to stress, but not in the same manner. Br Med J, Vol. 288, #6435, p. 1950, 1984.

HEROIN OVERDOSE:

Twenty patients experiencing heroin overdoses were treated with the standard narcotic antagonist naloxone (Narcan) or with physostigmine, the reversible esterase inhibitor. All patients reponded to therapy were conscious and breathing spontaneously within ten minutes. Physostigmine did not produce signs of opiate withdrawal in those considered abusers of the drug while those symptoms were apparent in the naloxone treated group. Additionally, physostigmine's beneficial effect is more short-lived than that of the narcotic antagonist. *Clin Toxicol*, Vol. 21, #3, p. 387, 1984.

AFFECTIVE DISORDERS:

It has been postulated that an imbalance between the parasympathetic and sympathetic portions of the central nervous system may be involved in the pathogenesis of manic-depressive illnesses. Fibroblasts from patients with affective disorders were studied and found to have a greater density of muscarinic receptors than did those of normal controls. Depressive episodes have been associated with both acute and chronic exposure to cholinergic agents as well as cholinesterase inhibitors such as parathione. There is some indication that the increased density of receptors is genetically acquired. *N Engl J Med*, Vol. 311, #4, p. 225, 1984.

HYDRALAZINE:

Hydralazine (Apresoline) has been found to interact with foods in such a way as to reduce its antihypertensive effects. The reduction of activity cannot be explained by a reduction in hepatic function so investigators have suggested that food increases the intravascular conversion of hydralazine to an inactive metabolite. Clin Pharmacol Ther, Vol. 36, #1, 1984.

AMIKACIN:

Aminoglycoside antibiotics are known to be extremely water soluble and thus depend on renal function for elimination. It is now apparent that approximately 10% of a dose is not eliminated during the first six hours after administration. Investigators feel a significant amount of the drug is secreted into the bile and subsequently into the intestine. Concentrations of aminoglycosides, especially amikacin, can be achieved in the bile to make them effective in treating biliary infections. *J Clin Pharmacol*, Vol. 24, #5, p. 247, 1984.

DIGOXIN INTERACTION:

Digoxin levels can vary depending on concomitant drug therapy. Another regimen has been found which will alter the effects of this cardiac glycoside. When quinidine and spironolactone are used with digoxin, plasma levels of the digoxin should be monitored and dosage reduced if necessary. Controlled studies show the half-life of the glycoside increases when the cardio-vascular agents are used alone with it. *Clin Pharmacol Ther*, Vol. 36, #1, p. 70, 1984.

NORFLOXACIN:

Penicillinase-producing *Neisseria gonorrhoeae* are responsible for producing an increased incidence of gonococcal urethritis. A new antibiotic compound similar to nalidixic acid in structure was found to be as useful as injected spectinomycin in eradicating the causative organism. The drug, norfloxacin, was administered in two oral doses of 600 mg each. The doses were given four hours apart. Norfloxacin may be a valuable agent for oral use against penicillinase-producing gonococci. *N Engl J Med*, Vol 311, #3, p. 137, 1984.

ANTIHYPERTENSIVE THERAPY:

Animals were given various doses of hydralazine (Apresoline) and reductions in blood pressure were recorded. The intensity of the beneficial effects was increased when concomitant atenolol (Tenormin) was added to the regimen. The synergistic effects are seen most dramatically at low doses of hydralazine and disappears as the doses of that drug are increased. *J Pharmacol Exp Ther*, Vol. 230, #1, p. 205, 1984.

FORSKOLIN:

A diterpene derivative, forskolin, has been found to be useful in treating patients with congestive heart failure. The drug possesses an inotropic effect thought to be due to its ability to activate the adenyl cyclase system in the myocardial tissue. The drug may be more useful in eradicating myocardial inactivity if combined with a beta-adrenergic agonist. New treatments for congestive failure are being sought because of the low therapeutic index associated with the digitalis glycosides. *J Clin Invest*, Vol. 74, #1, p. 212, 1984.

GALLSTONES:

Women are more likely to experience gall stone formation, even at an early age. A case controlled study has concluded that some women are at a greater risk of gallstone formation and that the chances of stone formation increase with the use of oral contraceptives or when pregnancy was experienced. *Br Med J*, Vol. 288, #6433, p. 1795, 1984.

PROSTAGLANDIN D-2:

The most abundant prostaglandin in the human lung mast cell is prostaglandin D-2. Medical literature about this substance is not in abundance, but its role in respiratory tissue has been studied. The authors suggest that prostaglandin D-2 is at least partially responsible

for the bronchial constriction associated with allergic reactions in susceptible individuals. *N Engl J Med*, Vol. 311, #4, p. 209, 1984.

BECLOMETHASONE:

A decade has passed since beclomethasone (Beconase) was first used to treat asthmatic patients. It has fulfilled most of the predicted claims for it and has not been found to cause damage to tracheobronchial or nasal membranes. The inhaled form of beclomethasone does not affect the adrenal-pituitary axis and thus reduces side-effects associated with orally administered and most inhaled steroids. *Drugs*, Vol. 28, #2, p. 99, 1984.

BETA-BLOCKERS AND PLASMA LIPIDS:

The non-specific beta-adrenergic blocking agents have been found useful in preventing secondary myocardial infarctions. The full benefit of their action may not be realized as studies show increases in plasma lipids associated with beta-blockade may act to partially reverse their benefit. The drug used in this experiment, nadolol (Corgard), apparently causes a reduction in lipoprotein lipase activity thus allowing the fats to accumulate. *Br Med J*, Vol. 288, #6433, p. 1788, 1984.



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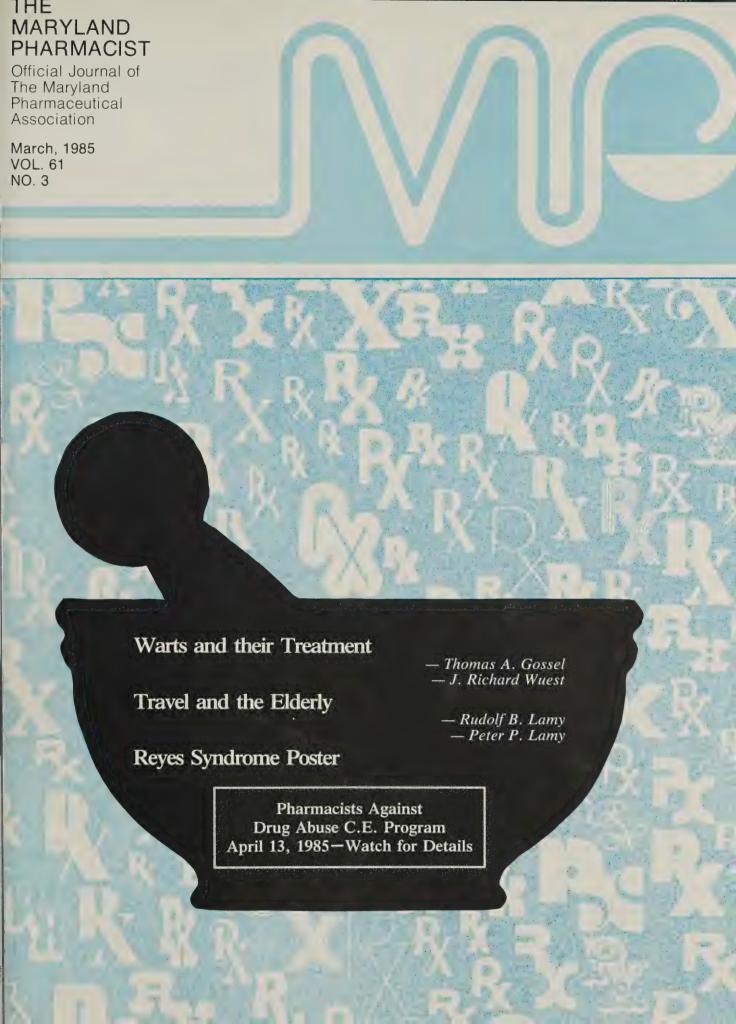


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national scene

MDs Negative on Cost Containment



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Health Cost Inflation Tamed?



Physician attitudes toward cost containment differ so greatly from those of the American public that the medical profession risks being seen as part of the problem when it could have been part of the solution. So says a major survey on physicians' attitudes commissioned by The Equitable Life Assurance Company. Most physicians don't feel the lack of competitive pricing among providers plays much of a part in the rising cost of

health care, the survey found, even though 77% of the public feels competition is important in keeping the price tag down. In addition, most physicians give thumbs down to preferred provider organizations (PPOs), health maintenance organizations (HMOs), prospective payment based on diagnosis-related groups (DRGs), and other emerging forms of cost containment.

Now there's data to support the long-held contention that drugs are generally the least expensive form of medical therapy. A series of studies conducted under the auspices of the Pharmaceutical Manufacturers Association (PMA) demonstrate that drugs cut health costs because they reduce the need for alternative, more expensive therapy such as surgery and hospitalization. One drug alone—the

beta blocker timolol—could save as much as \$3 billion a year when used to prevent second heart attacks, one study found. In addition, PMA noted, drugs represent a steadily declining portion of the health care dollar. In 1982, drugs accounted for only 6.9% of total U.S. health expenditures—a fact those who are working to contain health care costs need to be continually reminded of.

Supply and demand for pharmacists are projected to even out over the next two decades and be roughly in balance by the year 2000. So says the latest report from the Federal Health Resources and Services Administration. There will be an excess of pharmacists for the immediate future, says the report, but notes that the surplus won't be nearly as great as that

for some of the other health professions, such as medicine and dentistry. However, decreased enrollments at health professions schools in general are expected to take care of the overall problem. Pharmacy schools, by the way, have suffered the largest declines in enrollment of any professon over the past few years.

The rate at which health care costs are escalating has dropped significantly, giving hope that the health care inflation that has raged virtually unchecked for years may yet be tamed. The rate of inflation in medical care costs is now near 6.3%—about half of what it was when the Reagan Administration took office in 1981. However, this figure still

outstrips the overall Consumer Price Index by nearly 2%. The White House credits its Medicare diagnosis-related group (DRG) reimbursement plan for much of the success, though others also note a general moderation of inflation overall and a slackening demand for in-patient hospital treatment.



SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 1

Warts and Their Treatment

by Thomas A Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, OH
and
J. Richard Wuest, R.Ph.,
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Cincinnati, OH

Goals

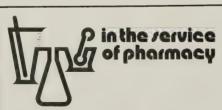
The goals of this lesson are to:

- discuss the etiology and treatment of warts;
- review the pharmacology and therapeutics of OTC and prescription remedies for warts.

Objectives

At the completion of the lesson, the successful participant will be able to:

 choose the appropriate OTC and prescription agents for treating warts;



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC. © Merrell Dow 2. explain the proper technique for applying these OTC and prescription agents.

Introduction

In this month's lesson, we bring the good news that kissing a toad will not cause warts. Likewise, rubbing warts with a stolen dishrag at midnight under a full moon is not a cure! Warts have fascinated mankind for many years and have been the subject of volumes of publications speculating on their causes and treatment. Their role in providing a form of visual punishment to the bearer for some ill-done deed is well documented in folklore. Even the medical literature, through the first quarter of this century, declared that little was known about warts and that their treatment was, at best, symptomatic.

Today, we know that viruses cause warts. We also know how to approach treating them. Treatment is not always totally complete, but various methods are at least directed toward the correct cause — viruses.

This month's lesson reviews the etiology, characteristics, and treatment of warts. Most importantly, it discusses specific patient advice a pharmacist should convey to consumers who wish to self-treat warts.

Etiology of Warts

Warts are benign papillomas (non-cancerous elevations). They are caused by epidermotropic DNA human papovavirus (HPV). This means they only affect the epidermal layers of skin and do not invade the deeper layers, and that they take over the DNA synthesis mechanisms in human cells and cause them to manufacture these substances for their own reproduction.

At least eight strains of wartcausing viruses have been positively identified, but it is speculated that there are several other strains th will be distinguished in the futur HPV is specific to human cells ar has not yet been isolated from no human tissue. Thus, attempts grow it in vitro in non-human tissucultures for purposes of study han not yet been successful. This has been the greatest handicap thus f in assessing why we are still decient in important information abowarts.

HPV viruses are also specific as the types of warts they cause. For e ample, HPV 2 causes most common warts. HPV 3 is the source of plan warts. HPV 2 and HPV 6 are the fators involved in most anogenial wart formation. Other warts may caused by a combination of the viruses. It is not known just how the various HPV strains relate, if at all, specific areas on the body, or to the appearance and clinical outcomes warts.

Warts, as with most other viral ifections, are contagious. They cappear on adjacent fingers or toes can be transmitted to other peopeither through contact, or by indiremeans such as public showers a swimming pools.

The incubation period for wa varies from one to twenty month the average time is three to formonths. They may occur on a area, although they are most comon on pressure points, areas scratching, and other sites of irrition. Trauma is thought to be one the etiological factors that stimula the wart-causing viruses to be their activity.

Persons of all ages may get was They are most common in the terage years, and rare in babies and vayoung children. It is reported that percent of all teenagers have was More than 20 percent of the popution may be continually bothered them. Almost everyone will have or more warts sometime dur his lifetime.

Persons of all cultures reprenting all countries of the world get arts. They occur more commonly persons engaged in certain occutions. For example, individuals ch as butchers or fish handlers no work around moist areas are at gh risk for developing warts on eir hands and arms. Furthermore. rsons with certain immunological ficiencies such as those encouned in Hodgkins's disease, and ose individuals on chronic immusuppressant therapy have a greater cidence of wart development. ey also respond poorly to drug atment.

Warts may increase in size during egnancy, and genital warts are one common during the active sexyears.

pes of Warts

Common Warts (verrucae vulis). Common warts are the most quently seen warts. They are preninant on the hands and around nail beds, but can appear anyere on the body. They sometimes erge around the genitalia, but ould not be confused with genital rts. Most measure 1 mm to 2 mm liameter, are rounded or irregular shape, and have a rough surface. common warts are light grey to low-brown in color, occasionally earing grayish-black. When they ken, it usually means that tiny od clots are underneath the sur-E. These warts will bleed on reval. Common warts usually occur multiples, although single warts frequently seen in older people. eriungual Warts. A periungual t refers to those found specificalround the nail plate. They are frently associated with nail biting. y are also usually resistant to tment. When severe, periungual ts may increase in size sufficiento cause the nail plate to actually arate from the finger.

lantar Warts (verrucae itaris). Plantar warts are occaially mistaken for corns or callus-They appear on the plantar (bot-) surface of the feet. Plantar warts ound and rough, and may be soft rm. They do not protrude above skin's surface. Most people have one plantar wart at a time. aligned together, they are termed mosaic warts. Plantar warts can be distinguished from corns and calluses by pressing on their outer edges with a knife blade. Plantar warts have a soft inner core. Corns and calluses have a hardened inner area. Plantar warts frequently turn black and become painful just before their normal resolution.

Plane Warts (verrucae planae). Plane warts, also called flat warts, commonly appear on the forearms, backs of the hands, the face, and the knees. They are small, rarely exceeding 1 to 5 mm in diameter. They appear as flat or slightly elevated lesions that are slightly off-color and may be readily mistaken for a rash. Plane warts may redden and begin to itch with even greater intensity just before disappearing.

Anogenital Warts (condyloma acuminata). Anogenital warts are those that appear on the anorectal area or genitalia. They appear as a cauliflower-like structure, often measuring 2 to 3 cm in diameter. They are soft, pink, and usually confined to external areas, although they may occur within the vagina or anus. Anogenital warts are extremely painful and are readily contagious. They are usually spread by sexual contact.

Digitate (filiform) Warts. These appear as long and thin thread-like structures. They are usually seen on the face around the nose and mouth. They are most common in boys and young men.

Treatment

Most warts disappear spontaneously, months to years after they appear. Warts in multiples may disappear one at a time or all at once. In one survey of more than 1,000 children who had warts, 54% of them noted that the warts disappeared within a year of first being noticed. Sixty-seven percent experienced disappearance of their warts within two years.

Warts do not disappear over night, contrary to what some people believe. When an individual reports that such quick resolution did occur, it is just that the person has failed to notice the slow process over the previous several weeks, months, or years.

Warts seldom return at the same location. However, on occasion they do. When this occurs, the individual's immunity that developed against the warts was probably not complete. Conversely, the new wart may be caused by a different strain of HPV.

Immunological Defense. The body's immunological system is responsible for warts disappearing. The body forms a localized cell-mediated defense mechanism rather than a generalized reaction as it does with systemic bacterial infections. Thus, circulating antibodies are not found when warts have disappeared.

Warts seldom require medical treatment because they heal spontaneously. However, when they impair normal functions, are cosmetically unacceptable (e.g., on the face), or are extremely painful, they should be removed. Only a physician should attempt to remove warts on the face or anogenital area.

Avoidance of scarring and permanent damage to surrounding tissue should be the primary goal of therapy. If scars form on a weight bearing surface, they can cause a lifetime of pain and discomfort. If this goal must be compromised, no treatment should be undertaken.

The treatment of warts is dependent upon establishment of immunity, and no treatment will be effective until this occurs. Some treatments provide palliative relief of symptoms and are, therefore, logical. However, most treatments may be viewed as "buying time" until the body's natural immunity is established. Many attempts have been made to correct this immune deficiency or to alter individual responses. However, none have thus far been successful.

The absolute "cure" for warts occurs when the affected person develops a natural immunity. Many studies have shown that the peak concentration of virus in most warts occurs when the warts are about sixmonths-old. The body may require another six to twelve months to produce sufficient antibodies to combat these viruses. Topical therapy will not help stimulate formation of these antibodies, and some authorities have cautioned that premature destruction of a wart may enhance reinfection. Thus, there are strong arguments for leaving a wart alone, at

least until this immunity has occurred (at least six to twelve months after the appearance of the wart).

The FDA advisory panel that reviewed OTC wart removers suggested that common warts and mild plantar warts can be self-treated with OTC medications.

OTC Wart-Removers. The above mentioned advisory panel has recommended that salicylic acid (in concentrations of 5 to 17% in flexible collodion) should be classified as a Category I agent (i.e., safe and effective) for removing warts. No other substance was so designated. Other ingredients of OTC products evaluated by the panel are listed in Table 1.

TABLE 1 Wart Remover Ingredient Classification*

Classification			
Classification	Ingredient(s)		
Safe and effective (Category I)	Salicylic Acid		
Either unsafe or ineffective (Category II)	Benzocaine Camphor Castor Oil Iodine Menthol		
Needs more study to prove effectiveness (Category III)	Acetic Acid Ascorbic Acid Calcium Pantothenate Lactic Acid		

*as recommended by an FDA advisory panel.

Salicylic Acid. Salicylic acid is a keratolytic (peeling) agent which softens and destroys cells in the outer layer of skin. This action is thought to result from increasing endogenous hydration of the tissue, most likely by lowering its pH. By causing a dissolution of the skin's intracellular cement substance, keratin becomes swollen, softens, and sheds.

The advisory panel made special note about collodion and its component, the nitrocellulose derivative, pyroxylin, as a vehicle for salicylic acid. Recall that pyroxylin contains the volatile solvents ether and alcohol and the plasticizers camphor and castor oil. Applied to a wart, the solvents volatilize leaving behind a layer of pyroxylin as the insoluble water repellent film. This ensures a close contact between the medication and wart, and therefore, complete absorption of the active drug into the affected tissue. Because of the nature of its rigid film, accidental drug loss due to run off onto surrounding tissue is minimized.

Category II Ingredients. Benzocaine, camphor, castor oil, iodine and menthol were all listed as Category II because they lacked data demonstrating either safety or effectiveness when used in OTC wart remover products. However, several of them may be retained as "inactive" ingredients.

Category III Ingredients. Included as Category III ingredients were acetic acid, ascorbic acid, calcium pantothenate, and lactic acid. The advisory panel indicated that each of these agents required more study before the agent could be listed as effective. They are all safe, but they cannot be proven effective OTC wart remover ingredients.

Lactic acid is of special interest. This has long been used in wart remover products and is currently employed in numerous formulations in 2 to 10% concentrations. The substance has not been demonstrated to be an active keratolytic agent alone, but there is some evidence that it indirectly influences the keratinization process. Furthermore, all current data that discuss lactic acid as a keratolytic for wart removal were obtained from studies in which it was combined with salicylic acid. The advisory panel recommended that specific studies are needed to clarify the effectiveness of lactic acid used alone.

Manufacturers of products that contain Category III ingredients are currently in the process of gathering data to establish effectiveness of these ingredients. Meanwhile, products containing Category III ingredients can continue to be marketed until FDA formally acts on the panel's report.

Prescription Drugs

Several agents that require a prescription are included to complete this discussion.

Cantharidin ("spanish fly") is a potent keratolytic that induces epidermal cell separation and destroys the wart. It will also cause similar damage to healthy tissue. Therefore, most physicians prefer to apply it themselves rather than prescribe it for self-treatment by the patient.

Currently, it is prepared as a 0.7% solution in equal parts of flexible collodion and acetone. A few drops are placed on the wart and covered with non-porous tape. The patient is advised to remove this tape after a day or so and replace it with a loose bandage until the next office visit usually a week later. One treatmen is normally sufficient. However some will need a second application

While pain is not noted immedi ately following its application, can tharidin does cause mild to moder ate pain 12 or so hours later in up to 50% of individuals treated. In the event that this occurs, patient should be advised to take OTC anal

gesics as needed.

Mono-, di-, and trichloroaceti acids are generally reserved for large recalcitrant warts that appear on th feet and anal areas. These acids ar extremely caustic and require subse quent applications. Therefore, som physicians will prescribe them for the patient to apply at home.

Patients using a medication the contains one of these acids should b advised to cover the surrounding tis sue with petroleum jelly before ap plying the acid. Any normal tissu that comes in contact with the proc uct should be immediately and tho oughly flushed with water an washed with soap. Applying a slurr of sodium bicarbonate following th procedure will help neutralize ar remaining acid.

Podophyllin (usually prepared tincture of benzoin) has been show to be useful for warts in moist area It should be used with caution c genital and anal warts, but many a thorities rate it as the agent of choice for warts in these areas. Suggeste therapy consists of applying the product, leaving it on for about hours, washing the area, and the applying more medication. This ma be repeated as often as needed.

Additionally, other treatments 1 quiring physician supervision i clude acyclovir, retinoic acid, idc uridine, methotrexate, formaldehy or glutaraldehyde, and fluorourac Appropriate advice for each of the agents should be passed on to the I

Formerly, x-rays were used to tre warts. Today, most authorities gen ally agree that the risks of excessi radiation exposure far outweigh poential benefits. Warts can also be cut off, burned off, or frozen with liquid hitrogen or dry ice.

Consumer Advice

It is important that consumers our chasing wart removal products inderstand that warts which are elf-treatable will generally disapear spontaneously even without reatment. Anal, genital, and plane varts, as well as any wart on the face hould not be self-treated with OTC roducts. Diabetics and others with hronic diseases of the circulation hould not attempt to self-treat their varts.

When a wart remover is desired, he individual should be advised hat compliance is mandatory, that he medication must be applied extly as directed, and that a dermalogist or podiatrist should be possulted if no improvement is not after a month or so of therapy. If cessive irritation occurs, the medi-

cation should be immediately discontinued. Commercially available products at the time of preparation of this lesson are listed in Table 2.

Warts that are larger than 1 cm in diameter, occur in multiples, or are involved with inflammation should not be self-medicated. Rapidly growing warts, those discharging fluid or blood, and those that have failed to respond to previous treatment should likewise not be self-medicated. All of these require diagnosis and treatment by specialists who fully understand the proper therapy of warts.

In any instance, proper hygiene is essential since warts are contagious. The hands should be washed well before and after treating warts, and separate washcloths and towels should be used. If the wart is on the sole of the foot, it is unwise to walk around barefooted.

Additional advice for patients comtemplating purchase of an OTC wart remover product is listed in Table 3.

TABLE 2
Representative OTC Wart Remedies

roduct	Dosage Form	Salicyclic Acid Concentration (%)	Other Ingredients*
alicylic	Cream	10	_
ompound W	Liquid	14.2	acetic acid
ff-Ezy	Liquid	17	_
ergo	Cream	-	ascorbic acid and calcium pantothenate
eruka-10	Liquid	10	lactic acid
/art-aid	Cream	_	ascorbic acid and calcium pantothenate
/art-Off	Liquid	17	_

effectiveness will need to be proven for manufacturers to continue to claim these ingredients as active.

TABLE 3 Patient Advice

- Since treatment may take six weeks or longer, compliance with therapy is extremely important.
- Apply the medication exactly as directed.
- Do not cut, scrape with a sharp instrument, or scratch deeply into the wart area.
- Wash hands before and after treating a wart.
- If a wart shows no improvement after
 weeks of treatment, see your doctor.
- Discontinue use of this medication if excessive irritation occurs.
- Do not apply a wart remover product to moles, birthmarks, or unusual looking warts with hair growing from them.
- Apply petroleum jelly around the wart to protect surrounding tissue from accidental application of the wart remedy.
- If the wart is being treated or appears injured, use a separate towel and wash cloth for cleansing the wart area.
- When warts are present on the feet, do not walk barefooted.
- For solutions: Apply one drop at a time. Wait for it to dissipate over the wart, then apply another drop if necessary. This minimizes spread (contamination) of the surrounding skin. Keep out of reach of children.
- For volatile solutions: Keep away from heat and open flames. Recap tightly after use. Keep out of reach of children.



Add this Information to Your Third Party Chart

Maryland Blue Cross Rejection Codes

0070 Error in date of dispensing (ie: June 31, 1992)

0110 Invalid sex code

0180 Amount of quantity is missing from claim form

0655 Invalid NDC number

0660 Contraceptives not covered

0670 Pharmacy number is incorrect or missing entirely from claim

1500 Duplicate drug claim for a claim already paid, rejected or in review

1510 Subscriber's membership status not approved for drug coverage

1520 Same as 1510

1530 Drug dispensed prior to or after the effective date of drug coverage

1535 Date of dispensing is later than current paid to date.

1540 AWP is greater than 25% of allowable cost

1550 Member's eligibility is being changed

1600 Drug is not covered by plan

1630 Claim has been paid previously. Check payment vouchers.

1640 Amount due is less than cost minus deductible

1996 No matching membership number for submitted drug claim

7000 Pending payment or rejection. In progress/review

Questions regarding rejected claim forms may be directed to Ms. Pat Hauch at Blue Cross & Blue Shield: (301) 494-5673.

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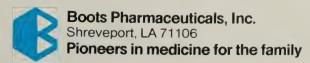
Check with your wholesaler for your exact savings; but here are some typical examples.

Product	Size	A.W.PRufen Direct Cost-Motrin	Savings	
RUFEN 600 mg	500	\$ 67.20	\$26.80 (29%)	
MOTRIN 600 mg	500	\$ 94.00		
RUFEN 600 mg	100	\$ 15.12	\$ 4.53 (23%)	
MOTRIN 600 mg	100	\$ 19.65		
RUFEN 400 mg	500	\$ 48.00	\$18.00 (27%)	
MOTRIN 400 mg	500	\$ 66.00		
RUFEN 400 mg	100	\$ 10.80	\$ 3.05 (22%)	
MOTRIN 400 mg	100	\$ 13.85		

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^{**}Redbook, August 1984.

Travel and the Elderly

by Rudolf B. Lamy

Any older person may be thought of, individually, as not really being old somehow. As a group, though, the elderly are still being pushed into the familiar stereotype. The reality may be quite different.

The majority of older people feel that they are fairly well off and describe themselves as healthy people who do not feel old or think of themselves as old in any sense of the word.

The educational and income levels of elderly people are rising. Elderly are healthier and more mobile than elderly in prior decades.

It seems that many elderly are taking advantage of their economic and social opportunities. For example, they are travelling further and in greater numbers than ever before.

A study was performed to elucidate the travel habits of a selected group of elderly. The study is limited by its scope and by the group of elderly interviewed who represent mainly middle- and upper-middle class suburban living white elderly.

For the purpose of this study, the poor and infirm were not included, but only older adults who have the health and discretionary income to allow them to travel were studied.

Sources of information included appropriate agencies and organizations such as the United States Department of State, Bureau of Passports, and the Department of Commerce, Bureau of Census, the AARP, the Gray Panthers and others.

More information was obtained from a review of the literature, focusing on subjects such as travel, retirement and leisure, using facilities like the AARP Resource Center. Personal contact with gerontologists and communication with centers for the study of aging and the elderly provided still more information.

Interviews with elderly people were conducted using a questionnaire developed to be a guide during interviews. The questionnaire was pretested. The people interviewed were drawn from family and friends and those recruited with the help of the Social Director of the apartment complex where the author lives.

The specific group studied was white, middle to upper-middle class and suburban. Statistically they are 60% female. All are American citizens but 50% have been naturalized. They range in age from 57 to 87 years with a mean age of 60.7 years.

Ninety percent of the study group are now participating in some form of leisure-travel activity. Further,

their rate of recreational travel has increased steadily over the past decade. Ten percent of the study group did no travelling at all. The rest of the group described themselves as frequent travellers. The usual number of trips a year is three, with an average trip time of two weeks. While 40% of the group have taken impromptu trips, the vast majority of travel is well planned. Most of the information for travel comes from travel agencies and airlines.

Of all those in the study group who do travel, all travelled within the state of Maryland. Within the state roughly 75% of all trips were taken with family or friends as travel companions, while 30% were trips to go to see family or friends.

More of the group travelled outside the 48 continguous states than do inside them. Of the entire group, 90% have travelled to Canada, Mexico, Hawaii, Bermuda or the Caribbean. All these trips have been strictly pleasure trips consisting of mostly family groups. Most often the families take organized group tours rather than just going on their own.

Trans-Atlantic, Trans-Pacific and South American travel were not quite as popular as trips closer to the United States. Only 80% of the total study group have made these types of trips. The method of travel was air as often as ship. Usually these trips were some sort of organized tour which had a combined air/cruise ship format, with South American travel having cruise ship stops at Caracas, Venezuela. Ten percent of the group have visited family in Europe and 10% have been on an individual trip to Australia.



Mr. Lamy is currently enrolled in the Graduate School, University of Maryland at College Park, College Park, Maryland.

In order to determine whether long-distance travel, outside the United States was as prevalent as the study group is indicating, a check of passport records was made. In 1960, the number of passports issued to people 50 and over was 343,000 out of a total of 853,000 issued. By 1982, the number of passports issued to older adults had risen to 1,300,000. That translates to a 26.38% increase over 22 years. The total number of passports issued in 1982 was 3,764,000. The number of total passports issued increased 22.66%. Older adults account for more than the average increase in issued passports over the period 1960–1982, which shows a trend of increased travel by the elderly and supports the statements of the study group.

Apparently, elderly travellers are not allowing their age to affect their travel plans. They are not taking tours or cruises designed specifically for elderly people. The study group, for the most part, does not require special travel arrangements or accommodations. It is apparent

that older adults do not fit the stereotype American society has cast for them.

There is no one reason why the older adult travels. Kastenbaum lists four reasons for travelling: "We've owed ourselves this trip a long time!", "I can't take another winter here!", "I want to try out a few places", and "I'm looking for a new life; the old one is gone."

It was most interesting to note that, except for organizations dedicated to the elderly, such as the AARP, nobody seems to have targeted the elderly traveller for any kind of marketing. If the results of this limited study are valid and could be replicated in a larger study group, it is reasonable to see the elderly targeted for special efforts soon.

If, indeed, the study group is representative at least of white, middle- and upper-middle class suburban-living elderly, than this constitutes a vast number of potential and actual travellers.

Travel and the Elderly: Implications for the Pharmacists

by Peter P. Lamy, Ph.D.

Recent articles in the Baltimore Sun and the New York Times validate the findings of the study presented in the preceding paper. Obviously, older adults travel, and travel in great numbers to distant countries, for whatever reasons. Quite obviously, this presents an opportunity for the community pharmacist to extend services that are somewhat unusual but may be most helpful.

Before Travel

What country is the destination? In some parts of the world, diseases such as measles, poliomyelitis, typhoid fever, viral hepatitis, and malaria occur in either endemic or epidemic form and, therefore, pose a threat to the traveler's health. Precautionary measures may then be indicated. For example, prophylactic doses of certain drugs are recommended to avoid malaria. One of these drugs is chloroquine. The pharmacist then needs to advise the patient that concurrent administration of certain drugs, such as antithyroid medicines, estrogens, oxyphenbutazone, phenylbutazone, and sulfonamides may enhance the risk to dermatitis, to which

the elderly are already at higher risk. Alcohol should not be consumed when taking chloroquine and it is, of course, important to note whether the patient already has been prescribed this drug for arthritis. Side effects to this drug to which the elderly may be more susceptible include diarrhea, other GI disturbances, ocular disturbances, and dizziness. In some areas of the world giardiasis is more prevalent than in others (possibly transmitted through fecally-contaminated water) and elderly on phenytoin would be at still higher risk. Symptoms include abdominal cramps, fatigue, diarrhea, and nausea, and may well be ascribed to "traveller's diarrhea".

If that diarrhea is treated with one of the recommended substances which contains bismuth subsalicy-late, and the patient is already on salicylates for an arthritic disease, the total intake of salicylate may be enough to cause acute salicylate poisoning, to which the elderly, more so than younger adults, are at risk. Many elderly ask questions about their routine medications, particularly if they include narcotic analgesics. In general, these present no problem when taken through customs, if they are labeled correctly. Some older adults take the additional pre-cautionary step of taking along a written statement from their physician indicating the need for the medication. Foot care becomes especially important for elderly travelers, particularly the diabetic patient. Insoles may be suggested,

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as may be a supply of band-aids, and an antibiotic ointment to treat any developing problem. Foot powder should be liberally used and feet inspected daily.

Lists of US-trained physicians in the country of destination can be obtained from the State Department or from US embassies abroad for those who may need the services of a doctor or dentist while traveling.

Medications should be packaged with particular care. A sufficient supply should be carried to account for possible loss of luggage which, unfortunately, still happens. Of particular importance, of course, is insulin. The importance of careful planning was underscored some time ago, when US travelers to Canada, still on U-40 or U-80 insulin, found that in Canada these specific dosage forms were no longer available. Planning ahead would also involve carrying an extra pair of glasses, hearing aid batteries and similar things. It would also involve checking whether canes can be carried aboard an airplane and whether transportation is available by a particular airline through crowded and immense airports.

Much has been published in the literature on preparation to avoid jet lag and it may pay to have this information available.

During Travel

Alcoholic beverages should be avoided but fluids should be consumed liberally, particularly by the elderly who are always at risk to dehydration. Food should be taken in limited quantities. Constricting garments should not be worn, particularly those which may constrict blood flow to the extremeties. Older adults should, if at all possible, try to move around every hour or so to help with circulation.

After Travel

This important area is quite often overlooked. Depending on the country visited, people may develop a diarrheal illness after return from an overseas trip. It is then important that these patients be referred to a physician as soon as possible, and self-treatment with diarrheal preparations should be strongly discouraged.

Conclusion

A few areas have been highlighted in which the community pharmacist may be of professional service to older adults about to travel or who have returned from travel. This is an as yet generally unrecognized area of service but one which will offer great opportunities to pharmacists inclined to expand their professional practice.

If nothing else, make sure your patient carries a record card listing all current medical problems and all current prescription drugs, as well as allergies and other problems. Warn the patient that in many foreign coun-

tries, drugs that can only be obtained on prescription here may well be available as non-prescription drugs and labeling may not indicate all ingredients. For example, antibiotic-containing cough and cold preparations are often available without prescription and those allergic to penicillin (or sulfonamides) must recognize that fact.

This and That About Pharmacy

by Leon Winer, P.D.

December Disaster-Special Notice-When I first read my "This And That About Pharmacy" in the December 1984 issue, I was deeply puzzled. How could the same errors reappear after they were removed? I had read the first rough draft of my report and found errors of spelling, punctuation, and omission. After calling these items into the office and having them corrected, I was even mailed the corrected report which I still have. Computers, word processors-they are all fine, but what about the human element? What if someone removes the uncorrect copy and sends it to the printer instead of the corrected copy. And this unfortunately happened! Well it is a serious matter, but nobody was hurt. Let us make light of it. As a matter of fact, let us say it is the Maryland Pharmacists's April Fool edition because by the time you read this, it will almost be April. Anyway, I think I have explained the matter to you and below are the corrections.

Report on Available Pharmacist Jobs: Correct sentence should be—If you wish to change jobs, this may be the time to make a move, and then again it may not be.

Report on Charles H. Tregoe: Correction should be LL.B. degree; examinations instead of examination; and FDA officer instead of officers.

Report on Hans Morgenroth: Correction should be two accidents, instead of accident.

Pharmacy Changes: omitted

Rite Aid #1492—New Pharmacy 1312 S. Main St.

Mt. Airy, MD 21771

Pharmacare Health Associates,

Inc.—Pharmacy Closed 901 Arcola Ave. Wheaton, MD 20902

Recent Pharmacy Deaths:

Samuel Markin, died September 22, 1984; age 70; graduated UofMD Pharmacy in 1914; omitted from past Maryland Pharmacist issue was "owned several pharmacies including Block Pharmacy in East Baltimore.

Joseph Parker, owner of Farlow's Pharmacy in Berlin, MD, could not believe what was happening to him. His store was quite busy and everyone worked hard, but the correct percentage of profit was down and not what it should be. He decided that shoplifting could be his problem. The past summer, he equipped his store with the checkpoint alarm system. That is a device that screens all persons leaving the store and sounds an alarm if someone exits without paying for an item. Within two weeks, the system uncovered five persons shoplifting and all will be prosecuted to the fullest extent of the law. Joseph, a native of Berlin, was hurt when he realized that it was not only customers, but people who he considered friends that were ripping him off. He told me if these people had said something to him, he would have lent them money or given them credit. Joe hopes that this will solve the problem since he figured shoplifters accounted for the loss of between \$20,000 and \$50,000 merchandise each year. Dr. Parker attended Johns Hopkins University for two years and the University of Hawaii for one year. He then went and graduated from the University of Maryland Pharmacy School in 1974 which also happens to be the year he bought Farlow's Pharmacy. He and his wife, Alana, have two sons, ages six and eight. When Alana, an attractive West Virginia girl, is not working as housewife, she is pitching in at the store as a bookkeeper.

PHARMACY CHANGES—December 1984

The following are pharmacies which closed in Maryland:

Santoni's Pharmacy 4301 Belair Rd. Baltimore, MD 21206

Poolesville Pharmacy 17710 Elgin Rd. Poolesville, MD 20837

Glen Vilah Community Pharmacy 12962 Travilah Rd. Potomac, MD 20854

Crest Pharmacy 7403 Liberty Rd. Baltimore, MD 21207

Drugfair #783 2451 Chillum Rd. Hyattsville, MD 20782

The following is a new pharmacy in Maryland:

Team Care, Inc. 6282 Montrose Rd. Rockville, MD 20852

A Big Birthday for a Pharmacist

(with words and pictures)

Since her brother, pharmacist Julian M. Friedman, was one half century old, Ellen Davis decided to throw an old time surprise birthday party for him on December 8, 1984. Jules was very surprised! That night, he was supposed to go out to eat at a Chinese restaurant with pharmacist Irvin Myers and his wife. However, Irv had



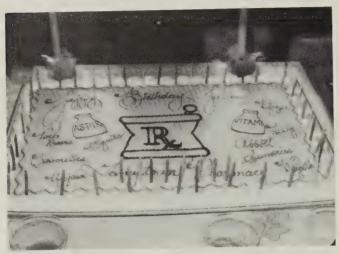
Jules enters and is surprised at his birthday party.

to drop off a package first at a house which just happened to be located next door to Jule's sister. As you can now surmise, nobody answered next door, so Jules volunteered to drop the package at his sister's house. Among the large gathering of people at his party were



Jules goes after the Balloon Girl. On left is Irv Myers, Pharmacist

pharmacists Walter H. Sachs and Kurt L. Sacki, both employed by Giant Pharmacy. Also, present were Fred Abramson, former owner of Eastern Pharmacy in Essex and now working part time at the University of Maryland School of Pharmacy. Features of the big night included a tremendous amount of good food, all kinds of drinks, and a large birthday cake decorated with pharmacy memorabilia. However, the main attraction was one of those singing telegrams. Dr. Jules had to break all the balloons which covered a beautiful young dancing girl who was clad only in a bikini. Never have I seen him move as fast as he did that night in his at-



Jules birthday cake—a big 50-years-old.

tempts to break all the balloons which he eventually did. Jules, University of Maryland 1956, is the owner of Taneytown Pharmacy in Carroll County near the Pennsylvania line. He is the son of late Nathan Friedman, pharmacist, who owned Friedman Drug Company Pharmacy for many years.

Love and Marriage

Harry Bass, P.D., and wife announce the wedding of their daughter, Deborah Sue, to Murray Alan Mease. Both Debbie and Murray are pharmacists of the University of Maryland, School of Pharmacy, Class of 1984. Harry, UofMD Pharmacy 1958, is a former store owner who now works for the Maryland State Department of Health and Mental Hygiene.

Erwin Deitch, P.D., and wife announce the wedding of their daughter, Rebecca Faye, to David Scott Leibowitz. Erwin, UofMD Pharmacy 1957, works for the Revco Drug Company.

Edward C. Esslinger, P.D., and wife announce the engagement of their daughter, Susan Jane, to Larry Wayne Betz. Plans are being made for a June 1985 wedding.

Edward, UofMD Pharmacy 1958, was employed many years at Blatt Pharmacy on Eastern Avenue.

Harold P. Levin, P.D., and wife of Reno, Nevada announce the wedding of their daughter, Ellice, to Mark Lewis Krivel. Harold, UofMD Pharmacy 1943, used to own MacLarty Pharmacy in northeast Baltimore City.

Harry Rochester, P.D., announces the marriage of his son, Dr. Stuart Rochester to Shelley Harris Golomb. Harry, UofMD Pharmacy 1939, used to own Rochester's Pharmacy on Reisterstown Road in Baltimore City.

William Weiner, P.D., and wife announce the wedding of their daughter, Francine Lee to Dr. William H. Taub. William, UofMD Pharmacy 1944, works for the Spectro Drug Company.

Recent Pharmacy Deaths

- Leon Goodman, P.D. Died January 16, 1985. Graduated UofMD Pharmacy 1941. Used to own Carter Drug Store in Baltimore City. At present time, was working for Associated Prescription Service (APS). Brother of pharmacist Irvin Goodman who owns Schmitt's Pharmacy in Westminster, MD. Member of the Wedgewood Club.
- Benjamin A. Krusniewski, P.D. Died December 25, 1984. Age 92. Graduated from Milton University, a now defunct college in Baltimore. Member of the Wedgewood Club and the Baltimore Veteran Druggists Association.

This column is very interesting in knowing if there are any pharmacists in the State of Maryland who are serious joggers and have entered the Maryland Marathon, Boston Marathon, etc. If you know anyone, please mail in this information. Also, I would like any information about items of human interest to pharmacy. Please mail all items to:

Leon Weiner 2704 Maurleen Court Baltimore, MD 21209



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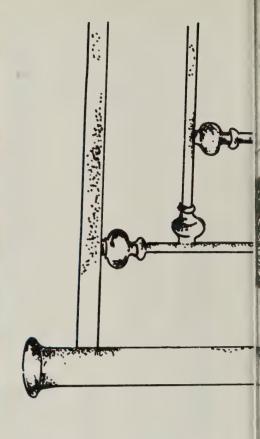
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A study by the Federal government's Centers for Disease Control has found a strong association between the use of aspirin in children with flu or chicken pox and the development of the potentially fatal illness



seems to be getting better.

 Do not use aspirin for children or teenagers with the flu or chicken pox without first consulting a physician. • If symptoms of Reye's Syndrome appear, immediate medical attention is required.



For additional information, consult your pharmacist.



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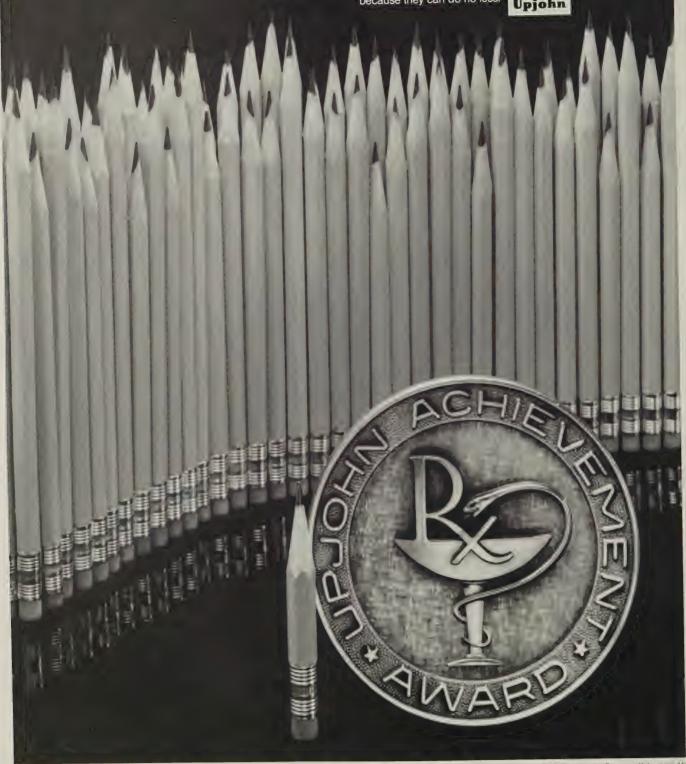
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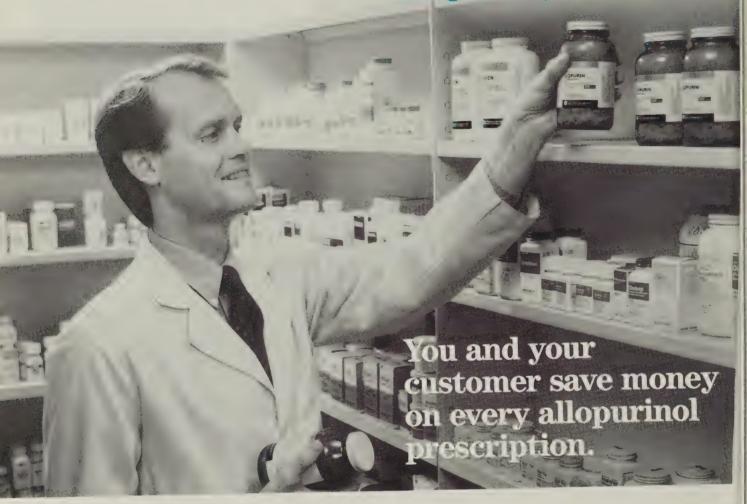


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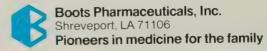
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One Degree or Two? Pharm.D. vs B.S.

by Hung-Hung Li*

In 1949 when the entry-level degree for the practice of pharmacy was the four-year B.S., the final report of the Pharmaceutical Survey recommended that pharmaceutical education switch to a mandatory six-year curriculum. The profession compromised with a five-year B.S. beginning in 1960. Now several schools offer only the Pharm.D. as an entry-level degree and several other schools including University of Maryland offer both a B.S. and a Pharm.D. degree. Should all schools offer the six-year Pharm.D. degree and eliminate the five-year B.S.?

In order to evaluate this question critically, it is necessary to define the roles and functions of the B.S. pharmacist and the Pharm.D. pharmacist and to determine society's needs for their services both at present and in the future.

Opinions on this subject of degrees vary widely among health professionals and educators. Some favor the Pharm.D. as the single entry-level degree for all, while others think of the Pharm.D. as an ego trip for some pharmacists to be called "Doc." Many recommend the two-tiered system and allow the students freedom of choice.

Those who favor the Pharm.D. degree say that the patients deserve the very best pharmaceutical care that the current state of the art allows. Gaining better skills in pathology, biopharmaceutics, and pharmacokinetics will enable the pharmacist to interact with patients and physicians more efficiently and thoroughly. They point out the fact that the number of schools offering the Pharm.D. degree is increasing. Individuals holding the Pharm.D. are preferentially offered employment in clinical and policy-making positions. Another argument for the Pharm.D. degree is that training at the doctorate level will increase the prestige of the profession. Pharmacists should be called "doctors" just like other health professionals. One single degree will serve as a unifying force and eliminate the concept of second-class professional practitioners.

Many practicing pharmacists feel threatened by the increasing number of clinically trained Pharm.D.s. "Where does this leave me?" asks the B.S. pharmacist. Some believe that a Pharm.D. is over-educated for many of the tasks that a pharmacist performs daily such as dispensing over-the-counter drugs. An extra year in school would be a waste of time, money, and academic

* Hung-Hung Li is a first professional year student at the School of Pharmacy, University of Maryland at Baltimore.

resources. Most pharmacists work in a community setting where clinical expertise is not essential. Some complain that an extra year of schooling does not warrant the title "doctor" and say that respect is earned through action and not by the title of one's degree. Others argue that the five-year program is more than adequate to prepare a student for a pharmacy career. More years of educations are not necessarily better. We should strive for quality rather than quantity. Many pharmacists do favor a curriculum that would place more stress on practice rather than on theory. They suggest courses in business administration, law, public speaking, and accounting.

Others warn about the dangers of adopting a Pharm.D. program too quickly. If colleges of pharmacy move rapidly to change to the Pharm.D. as the only professional degree, it is quite possible that the eventual outcome will be only a change in the degree with no improvement in the practice of pharmacy. California pharmacy practice has not changed significantly despite the large number of Pharm.D. degrees awarded there. Society has yet to begin to appreciate the value of a sophisticated clinical pharmaceutical practitioner.

Those who favor both degrees state that a two-degree program would prepare the student to practice in the community, hospital, industry, education, and research areas while minimizing over-qualification, under-utilization, and frustrations. There is room in pharmacy for both types of practitioners: the Pharm.D. in a clinical setting and the B.S. in a community setting.

The two-tiered system is the best solution for now (in the author's opinion) and adequately meets society's needs. However, as medical technology progresses and becomes more complex, the pharmacist will need more clinical training and knowledge. In time, the Pharm.D. may well become the single entry-level degree. But before that becomes a reality, the exact role of the Pharm.D. has to be defined and recognized by other professionals, especially physicians.

In today's society, people are more educated and sophisticated. Patients want to know more about drugs and their side effects. With the development of generic drugs and home health care, the pharmacist can play an increasingly important role in the health care system. The quality of his or her education should be a concern for all.

References available upon request

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Mail-Order Scripts Up Close and Personal

by Richard Harkness

Mrs. Peabody hands her new prescription order to the drug clerk.

"This will take a while, ma'am," the clerk says. "We're really snowed under."

So what's new? Mrs. Peabody thinks. Why don't they get more help?

Finally, the clerk calls her name and Mrs. Peabody waddles up to the cash register. The clerk rings up the amount.

"Oh, I almost forgot," says Mrs. Peabody. "Did you give me my senior citizen discount?"

The clerk gives her a pained look. Mrs. Peabody wonders why they can't keep a record of that.

"May I ask the pharmacist a question about my medication?" she asks timidly.

"Bill!" the clerk shouts at the pharmacist without looking up from the register void slip she is filling out. "Lady has a question. You got time?"

Mrs. Peabody hears the pharmacist mumble something. She waits several minutes before deciding he's forgotten her, and then walks out.

Actually, Bill had been on the phone. And then on the doctor's line right after that. He feels a twinge of guilt for not being able to get to the lady sooner.

That evening, Bill attends a local pharmacy meeting. The topic is how to combat mail-order prescriptions. Several pharmacists express their opinions.

One suggests that they should try to get mail-order firms outlawed.

"How?"

"Like some other states are doing. Use laws and regulations requiring out-of-state mail-order firms to have a state license and such."

"Hiding behind laws isn't going to work for long—that's a paper shield that'll rip apart when the big boys hit it. Mail-order is a wave of the future, I'm afraid. Government, big business, and insurance firms are all looking to contain costs, looking at that bottom line."

"Speaking of bottom-liners, some chains are thinking of jumping ship. Walgreen's has already gotten into mail-order out in Arizona."

"The chains know a trend when they see it, and they aren't going to be left behind."

"The chains will cope, as always. It's the independents who stand to lose."

"Too bad pharmacy can't stand together on this."

"Guess who the mail-order users are going to be calling for free advice whenever they have questions

about their medications?"

"Their local pharmacist, of course."

"One third-party administrator says that mail-order is the patient's refuge. He means that the patient is more likely to use mail-order if she's had unpleasant experiences with local pharmacies."

"We have to compete. Pure and simple."

"How?"

"One way is to present our side to the labor unions and companies thinking of using a mail-order firm. We could use something like the Maryland Pharmaceutical Association's mailing leaflet. It emphasizes the safety aspect and the face-to-face patient service and contact that only local pharmacies can provide."

That night, Mrs. Peabody reads a letter she received earlier in the day. It's from some company she's never heard of offering to fill her prescriptions by mail. They offer big savings, she notes.

The letter says, "No more walking, driving, or standing in lines, or waiting for a friend or relative to bring you the medicines you need."

She reads some of the other features of the service: computerized patient records (Her local Pharmacy doesn't have that, she thinks). Patient package inserts. Four checks of the prescription before mailing (That seems conscientious). Also, new prescriptions are required yearly to assure regular contact with the physician. And there's even a toll-free phone number to call to speak to a pharmacist if you have questions. A ten day wait is required (She's not crazy about that).

She remembers that her friend Gladys uses a mailorder prescription service. Gladys has a little plastic card she used to take to her local pharmacy. Then she received a letter from the company she works for saying she could help them cut costs (and thereby assure the continuation of her benefits package) by switching to mail-order. When that didn't sway her, the claims processor company itself sent her a letter (she termed it "nasty") telling her that their computer could identify any member not using the mail-order system when they should be. ("God, big brother really is here," she had said huffily.) Gladys felt like she had no choice, so she switched.

Mrs. Peabody knows she herself would feel uncomfortable letting some impersonal out-of-state mail-order place handle something as important as her medications. She'd never even see the pharmacist who fills her prescriptions. Yet, she has to admit, her local pharmacy really hasn't treated her much better.

Thank goodness she has freedom of choice.

National Symposium on Third-Party— April 24–25, 1985

The National Symposium to develop the pharmacy strategy for the "Challenge Of The 80s In Third-Party Pharmacy Programs" is being sponsored April 24–25, in Chicago, Illinois.

This National Symposium, designed expressly for practicing pharmacists, is being sponsored by the National Council of State Pharmaceutical Association Executives (NCSPAE). Serving as program chairman is Louis Sesti of Michigan.

This National Symposium is a first in American pharmacy to identify a pharmacy initiative regarding third-party... one which focuses on coordinated action rather than spontaneous reaction. This also is the first leadership-type program to plan strategies which invites practicing pharmacists to be directly involved in the process.

The National Symposum will feature keynote speakers on such critical subjects as:

- —The Forces of Change in this Health Care Revolution
- —Moving from a defensive attitude to an offensive game plan during times of opportunity
- -Behind-the-scene in the bargaining process

The National Symposium will also feature a Wednesday evening session on pharmacy introspections and current events. Thursday will be dedicated to special case study presentations of new programs being initiated across the country. It will conclude with the input of participating pharmacists to establish the national agenda.

Early pre-registration is suggested in the event attendance must be limited so that nationwide distribution is assured. The program is scheduled to begin at 1:00 p.m. on April 24 and adjourn by 3:00 p.m. the next day.

To pre-register send your name, address, city and state with a check or money order for \$50.00 per person to National Symposium: 156 East Market Street, Suite 900, Indianapolis, Indiana 45204. (The registration fee after March 1 is \$75.00 and attendance cannot be guaranteed if received thereafter.) Your pre-registration will be confirmed and you will be mailed advance information about the Symposium program.

P.S. The symposium will be held in the Westin-O'Hare Hotel, 5 minutes from the Airport. Specific details and Room reservation information will be mailed with the Symposium Registration Confirmation information. 10 hours of Continuing Education credit has been applied for—for each pharmacist participant.



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The 1985 Mid Year Meeting was held in Annapolis on January 27th. Dr. Jean Paul Gagnon, President-Elect of the American Association of Colleges of Pharmacy, delivered a presentation on Merchandising. MPhA President Ronald Sanford assisted with distributing the handouts.



As part of the Mid Year Meeting, the Pharmacy Achievement Scholarship Program honored participants. Here (left to right) Dr. Grady Dale presents an award to Earl M. Towers for his sponsorship of Scholarship Award Winner Roy Allen Slaughter



Donna Lewis, Burroughs Wellcome representative, congratulates Pharmacy Education Award winner, Mr. Joseph Schuman of the Maryland Rehabilitation Center as the Medical Director Rhodora Tumanon and Assistant Director Patricia Bennett observe.



Peoples Drug Stores was honored by the National Pharmaceutical Council for their participation in producing the public service television announcement, "Medicine and Your Good Health." Pictured are: (left to right) Dorothy Wade, Vice President of NPC; Mark Knowles, President of NPC; Sheldon Fantle, President of Peoples Drug Stores; Leonard DeMino, Vice President of Peoples Drug Stores, and Robert J. Bolger, President of the National Association of Chain Drug Stores.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

HYPOTHYROIDISM:

Patients with hypothyroidism show a reduction in adrenergic-like activity while those with a hyperactive gland show opposite symptoms. Studies conducted in neonatal animals indicate that biochemical and morphological changes occur in the adrenergic system of animals who are hypothyroid while in utero. These symptoms become more pronounced as the deficiency becomes greater. *J Pharmacol Exp Ther*, Vol. 230, #1, p. 53, 1984.

DILTIAZEM:

Although the calcium channel blockers have been approved for various uses, patients with other conditions resulting from excessive smooth muscle contraction have been given drugs within this group to see if their conditions would improve. Diltiazem (Cardizem) was found to be useful in reducing peripheral resistance, and thus may be beneficial in patients with mild to moderate hypertension. *J Clin Pharmacol*, Vol. 24, #5, p. 218, 1984.

CYPROHEPTADINE:

Cyproheptadine (Periactin) has been found to possess antiserotonergic, anticholinergic, antipruritic and antihistaminic activity. Studies conducted in vitro and in vivo suggest that the compound has an additional effect to inhibit calcium transport through membranes. The drug was found not to be as potent in this respect as the available calcium channel blockers, e.g. verapamil, nifedipine, and diltiazem. *J Pharmacol Exp Ther*, Vol. 230, #1, p. 103, 1984.

LEVONANTRADOL:

An analog of THC, levonantradol, has been compared to prochlorperazine (Compazine) in patients experiencing nausea and vomiting. The drugs seem to be equally effective but levonantradol produces more adverse reactions. Both drugs were responsible for producing somnolence, dry mouth and tachycardia while the TCH analog produced additional symptoms of postural hypotension, dizziness and blurred vision. *J Clin Pharmacol*, Vol. 24, #4, p. 155, 1984.

DIURETIC TOXICITY:

Long-term use of diuretics, especially loop diuretics such as furosemide (Lasix) and ethacrynic acid (Edecrin) can lead to the production of hyperglycemia. Since these drugs do reduce vascular volume, and since vascular volume depletion can be responsible for reduced organ perfusion, investigators designed a study to evaluate the role of fluid depletion in the development of

hyperglycemia. Data suggest that there are other factors in addition to reduced tissue perfusion which are responsible for the observed intolerance to glucose. Potassium depletion is thought to be contributory to hyperglycemia. *J Pharmacol Exp Ther*, Vol. 229, #2, p. 440, 1984.

HALOTHANE:

Halothane is a general anesthetic which has been used in patients with airway diseases such as asthma. Two patients undergoing surgical procedures were found to experience bronchospasm which did not respond to intubation and mechanical ventilation. Administration of halothane produced a favorable response. Although the beneficial responses may be expected in other patients experiencing similar problems, one must be cautious to guard against cardiac arrhythmias and hypotensive episodes which may develop in patients receiving halothane. *JAMA*, Vol. 251, #20, p. 2688, 1984.

GUANFACINE:

The antihypertensive effect of guanfacine has been investigated in both animal models and in human volunteers. The drug reduces the output of sympathetic tone from the central nervous system both when the patient is at rest and while performing isometric exercises. Guanfacine acts on alpha-2 adrenergic receptors in a manner not dissimilar to that exerted by clonidine (Catapres). Clin Pharmacol Ther, Vol. 35, #5, p. 604, 1984.

AMMONIA:

Normally the liver is quite effective in removing ammonia which is produced by intestinal flora and absorbed through the portal circulation. However, chronic liver disease decreases the efficacy of this process and increased levels of the ion appear in the blood. Hyperammonemia is associated with central nervous system toxicity, including hepatic coma. Since many drugs have been shown to have prolonged half-lives and increased effects in patients with liver disease, experiments were designed to determine what portion of the increased drug response might be due to reduced hepatic clearance of the drug and what portion may be due to the presence of the excessive ammonia. Drugs such as morphine, diazepam (Valium) and verapamil (Isoptin) were associated with increased activity. Investigators concluded that part of the potentiated response was due to the ammonia-induced blockade of calcium channels in tissues. J Pharmacol Exp Ther, Vol. 229, #1, p. 85, 1984.

PLATELET CALCIUM:

The concentration of free calcium in platelets has been found to correlate with the systolic and diastolic blood pressure readings. Patients who were successfully treated with antihypertensive agents were found to have the concentration of this free calcium reduced. It has been suggested that the same humoral or pharmacological factor which controls platelet calcium levels might also be associated with blood pressure regulation. *N Engl J Med*, Vol. 310, #17, p. 1084, 1984.

VALPROIC ACID TOXICITY:

Valproic acid (Depekene) hepatotoxicity has limited the usefulness of this drug and ways to prevent it have been investigated. It appears that the cellular damage is due to drug-induced lipid peroxidation of hepatic membranes. Investigators have suggested that simultaneous administration of free-radical scavengers such as vitamin E may help protect against this damage. *J Clin Pharmacol*, Vol. 24, #4, p. 148, 1984.

SODIUM THIOSULFATE:

Sodium thiosulfate has been used via slow intravenous infusion to reduce the toxicity of antineoplastic agents, especially the nephrotoxicity associated with the administration of cisplatin (Platinol). Sodium thiosulfate administration allows the antineoplastic agent to be used in more effective doses without the development of toxicity to the kidney. Clin Pharmacol Ther, Vol. 35, #3, p. 419, 1984.

WARFARIN:

Determining the appropriate dose of warfarin (Coumadin) to be used in patients requiring anticoagulant therapy can sometimes be a tedious and expensive procedure. Patients have been started on 10 mg. of warfarin and then adjustments made depending on results of prothrombin times obtained for four days. Using this method, investigators can determine the maintenance dose and thus reduce hospitalization and increase efficacy of the anti-coagulant. *Br Med J*, Vol. 288, #6426, p. 1268, 1984.

PROINSULIN:

Insulin is synthesized initially as proinsulin and it is then converted to the active molecular species by a specific enzyme system. Some patients with symptoms of insulin deficiency have been found to be deficient in the enzyme which converts the precursor to the active molecule. Genetic deficiencies may be responsible for symptoms of familial hyperproinsulinemia. N Engl J Med, Vol. 311, #10, p. 629, 1984.

VERAPAMIL:

The effectiveness of verapamil (Isoptin, Calan) in manic patients was compared to that produced by lithium salts and by placebo control. The results of this experiment indicated that the effects of verapamil and lithium were not only superior to that of placebo, but were comparable to each other. Since the therapeutic index of the calcium channel blocker is much higher than that of the lithium salt, further research into the antimanic activity of calcium channel blockers is warrented. *J Clin Pharmacol*, Vol. 24, #8 and #9, p. 400, 1984.

EXERCISE AND AMENORRHEA:

Women who strenuously exercise develop amenorrhea which has been attributed to deficiencies in gonadotropins. Investigators have found that these substances may have their plasma concentrations regulated via beta endorphin activity rather than by met enkephalin. The use of narcotic antagonists, such as naloxone, has been associated with reduction in the endocrine abnormalities thus suggesting the endorphine system has a wider influence on physiological parameters than originally anticipated. *JAMA*, Vol. 252, #10, p. 1258, 1984.

SULFISOXAZOLE SECRETION:

Sulfisoxazole (Gantrisin) is a drug which is bound to plasma protein to a great extent. Investigators were interested in determining if the kidney secreted only the free, unbound portion of the sulfisoxazole or if it has the ability to secrete the drug independent of its state of binding. Using animal models, it was found that renal tissue will secrete the sulfonamide independent of its binding to plasma protein. Thus the kidney seems able to remove the drug from plasma protein binding sites and secrete it directly into the urine. *Drug Metabl Dispos*, Vol. 12, #5, p. 607, 1984.

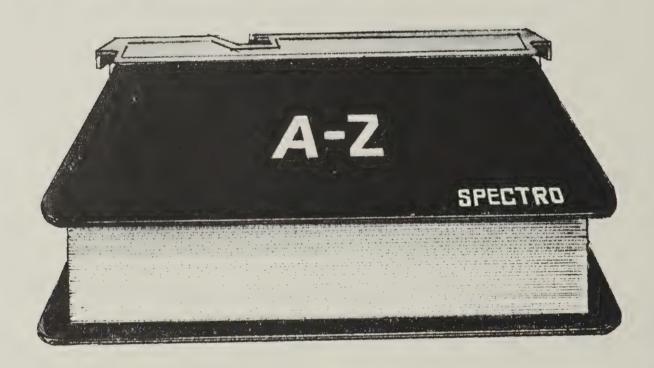
THIAZIDES:

Thiazide diuretics have been associated with cholecystitis, but the exact relationship was unclear. Studies conducted in Sweden indicate that the thiazides themselves do not cause the condition to develop, but may increase the risk of acute cholecystitis in patients with pre-existing gall stones. *Br Med J*, Vol. 289, #6446, p. 654, 1984.

CAPTOPRIL:

Captopril (Capoten) is an angiotensin converting enzyme inhibitor which has been used successfully to treat hypertension in dosage ranges of from 37.5 mg to 150 mg per day. Clinicians have found that higher doses of the drug are no more effective than lower ones in controlling blood pressure. They further indicate that the addition of a thiazide diuretic to the regimen will dramatically increase the efficacy of the captopril. *Clin Pharmacol Ther*, Vol. 36, #3, p. 307, 1984.

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Joseph Freiman, President of A.I.D. Drugs, Incorporated has announced the appointment of George P. Waldman as General Manager.

The association is a cooperative buying service comprised of forty independently owned and operated drug stores in the Baltimore area.

Mr. Waldman, of Ambler, Pa., brings years of experience in drug industry to his new position.

The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Cromwell Bridge Road Beltway Exit No. 29. For further information contact President Frank Block (phone: 358-2743). This organization has several veteran pharmacists available for part-time employment.

Pharmacy Position Available—Full time and part time position for staff pharmacists contact James Rutten—694-3392 or personnel dept—694-3550 Frederick Memorial Hospital.

The Baltimore VA Medical Center and the University of Maryland School of Pharmacy, Center for the Study of Pharmacy and Therapeutics for the Elderly, will sponsor a seminar on *Management of Cardiopulmonary Problems in the Aged*, at the Hilton Hotel on Reisterstown Road on Thursday April 18, 1985. This multidisciplinary conference will be directed toward physician, nurse, pharmacist and social work involvement in the special needs of the geriatric patient. For further information contact: John T. Jordan, R.Ph., M.S., Chief Pharmacy Service, VA Medical Center, Baltimore, (301) 467-9932, extension 5275.

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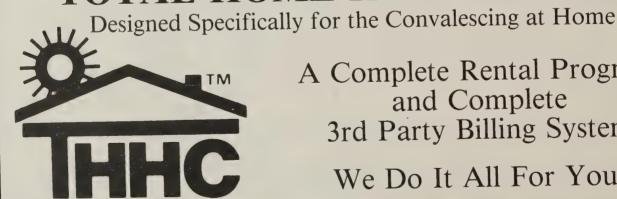


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THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

April, 1985 Vol. 61 No. 4



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THE MARYLAND PHARMACIST

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"A Far Fetched Idea or Maybe Not!

A great deal has transpired since my last president's message—the APhA Annual meeting—testimony before legislative committees—the raising of the ugly head of mail order prescription plans—to name just a few of our involvements.

Not unlike my earlier messages, I appeal to you for your suggestions, comments, criticism—your opinion!

I'd like to use my space this month to get on my soapbox about what I consider one of the critical issues that was raised at the APhA meeting—The Great Pharm.D. debate. Numerous questions come to the forefront:

- 1. Do we need *all* 6 year licensed pharmacists called Pharm.D.'s instead of 5 year B.S.'s.?
 - 2. Is the 5 year program really outdated?
- 3. Can the pharmacy "manpower crunch" handle the one-year lapse in the conversion if an all 6 year Pharm.D. happened?
 - 4. Can the colleges "absorb" the additional expense of another year?
- 5. What effect will 6 years have on enrollment? Can we compete with other 4 year B.S. Professional Schools?
- 6. How does the 6 year all Pharm.D. program impact on the existing "level" of Pharm.D. being graduated from UMAB and other institutions?

May I suggest an alternative? How about the following scenario:

- 1. 2 years pre-professional (as now)
- 2. 2 year professional (similar to now)
- 3. Award of B.S. Pharm. (note: not eligible to take State Board until completion of 5th year P.E.P)
- 4. 1 year P.E.P minimum of 3 rotations of community practice (certifies to take the Board exam)
- 5. Educational (1 or 2 or 3 year duration) in various specialities—e.g. clinical, Home Health Care, Hospital, manufacturing, administration, nuclear, etc. clearly established by university & Board of Pharmacy leading to specialty certification and the Pharm.D. degrees from the university. Additional Board certification of the speciality should be required. Perhaps this may seem far fetched but when the 5 year program was proposed the 4 year proponents felt 5 year was far fetched. Now that a mandatory 6 year program is considered perhaps "far fetched" yet very much under consideration. Perhaps my alternative could be worked with as a skeleton for a better "long range" goal then all 6 year Pharm.D.'s.

Are my ideas "far-fetched"? What are your ideas? What is your opinion, criticism or suggestion. As I have said before—let me hear from you.

Sincerely,

Ronald Sanford

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 2

Advising Consumers
on
OTC Personal Hygiene
Products

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Goals

The goals of this lesson are to:

- review the concepts of personal hygiene;
- explain how to advise patients on the selection of OTC personal hygiene products.

Objectives

At the completion of this lesson,



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC. © Merrell Dow the successful participant will be able to:

- recognize effective OTC personal hygiene products;
- 2. identify the pharmacological actions of the ingredients of these agents;
- 3. explain the proper technique for applying/administering these OTC agents.

Introduction

Personal hygiene is truly big business in the United States. It is estimated that Americans spend more than \$500,000 annually on antiperspirants and deodorants alone. Advertising experts on Madison Avenue have successfully sold the concept to Americans that perspiration and body odor (which are normal body functions) are socially unacceptable. This extravagant spending and preoccupation with body odor is not a new phenomenon, however. Egyptian, Greek, and Roman historians all described methods for masking body odor. For centuries the French have made a significant name in the Western world by perfecting and producing perfumed oils and waters.

Deodorants developed in the 1800's contained zinc oxide. Simple solutions of aluminum chloride and/ or iron chloride came in the 1900's. But, the major problem with these deodorants was that they were highly acidic, and irritated underarm tissue or ruined clothing. Aluminum chlorohydrate was introduced in the 1940's to help solve these problems; it and its derivatives have been the mainstay of commercial antiperspirant products since that time.

Deodorants Versus Antiperspirants. There are two types of products used for general personal hygiene: antiperspirants and deodorants. The basic difference between them is that **deodorants** either directly mask body odor or decrease the bacterial populations, in the un-

derarm area, that are responsible fo producing odor. They are considered by FDA to be cosmetics because they do not directly affect bodily activities.

Antiperspirants, as the name im plies, inhibit perspiration. They are legally classed as drugs because the do affect normal body actions. Antiperspirants will be the subject of thi article.

What Causes Sweating?

An explanation of sweat, its func tion, and what produces it is in orde before reviewing the active ingredi ents of antiperspirants. There ar three secretion (exocrine) glands in volved in sweat production: the apo crine, the eccrine, and the sebaceou glands (see Fig. 1). Sebaceous gland produce sebum, an oily substance that serves as a moisturizing ager for the skin. It holds sweat on th outer dermal layer of the skin so that the stratum corneum can be properl hydrated. Sebum also serves as a ni tritional source for bacteria that liv on the skin.

Both the sebaceous glands and the apocrine sweat glands open into hair follicles and release their secretions there. Most of the apocring glands are localized in the armp (axillary), perianal and nipple (areallar) areas. There is also a significan number of apocrine-like glands in the inner eyelid (conjunctiva) arear canal (ceruminous); the mammary gland is actually a modified apocrine gland.

The exact function of the apocrir glands has not yet been determine Elevations in the environment temperature do not increase their s cretions. Instead, apocrine glands s crete a slightly off-colored, lo volume, viscous fluid when they a stimulated by emotional stress sur as anger, fear, or pain. Direct m chanical pressure such as stroking petting also increases their secritions. Bacteria on the skin metab

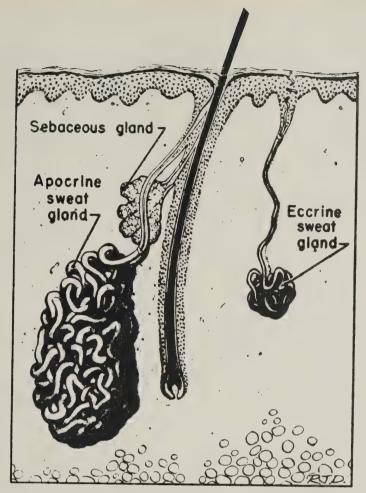


FIGURE 1. Glandular appendages of the skin.

ze materials in apocrine fluids to roduce an odor characteristic to ach individual. The current leading teory is that apocrine secretions omehow play a role in subconsious communication between huans.

Interestingly, most other mammals pecifically the lower primates) ive elaborate means of communiiting with each other via the sense smell. The fact that apocrine ands do not fully develop and nction until after puberty; that ev are located in warm, moist areas hich are very susceptible to bacteal growth; that they coexist with her (eccrine) glands which proice a high volume of sweat that aporates and, therefore, spreads e bacteria-produced odor adds bstance to the theory that these ands are involved in sexual attracn. The reasoning that the hair owing out of the follicles could rve as "wicks" for sending out the cretions adds even more credence this theory.

The other type of sweat glands lled **eccrine glands** are present in arly all areas of the skin. They open directly onto the skin and occur to the largest extent around hair follicles. Eccrine glands consist of a deeply coiled ductwork system located in the subcutaneous area that produces a watery secretion from plasma which is modified by the cells in the ductwork opening onto the surface. Eccrine sweat is composed of sodium, chlorine, potassium, urea, lactate, and glucose.

Concentrations of these various substances differ from individual to individual and the relative concentration of each constituent is modified by the rate of sweat secretion. During periods of rapid, profuse sweating, the concentration of each of these components will be much less than during periods of relative dormancy. Unlike the apocrine secretions, which rarely exceed a few milliliters, the eccrine glands can turn out as much as 12,000 milliliters of fluid in a twenty-four hour period. The average volume, however, is approximately one liter per day.

These eccrine glands are important in maintaining the body's proper temperature and electrolyte balance. Their activity is regulated by at least three known factors: thermal, mental, and a gustatory response. The hypothalamus contains the heat-regulating center. It, in turn, is activated or deactivated by the volume and temperature of blood circulating through its stem from the skin, and by antipyretic drugs.

Other areas of the brain are also believed to be involved in stimulation of eccrine glands, although the exact site of activity has not yet been determined. It is known, however, that mental stress increases sweat production, especially on the palms and soles of some individuals. The third regulatory mechanism, gustatory, has not yet been fully explained, but its existence is noted by the sweating that occurs around the mouth and on the forehead and nose after eating spicy foods.

There are various pathological disorders of the sweat glands. The more common ones are listed in Table 1.

TABLE 1 Disorders of the Sweat Glands

Anhydrosis: scanty or nonexistent sweat production. Results from CNS disorders or disruption of the autonomic nervous system. It is also a side effect of drugs with atropine-like effects (e.g. anticholinergics, tricyclic antidepressants, phenothiazines).

Bromhydrosis: bad smelling sweat.
Usually the result of improper hygiene but can be caused by volatile substances being picked up from the blood and secreted by the apocrine glands (e.g., garlic).

Chromohydrosis: colored sweat. Can be caused by metabolites of bacteria in the sweat duct or ingested dyes in drugs (e.g. rifampin).

Hyperhydrosis: excessive sweating.
Caused by both mental and systemic disturbances (e.g., malfunction of the hypothalamus, hyperthyroidism, diabetes, menopause, cancer, infections).

How Can Underarm Odor Be Eliminated?

While it is known that skin bacteria are the immediate cause of underarm odor, the exact species responsible has not yet been determined. Those that are undoubtedly involved include *Propionibacterium* acnes, *Propionibacterium* granulosum, var-

ious diphtheroids, and coagulasenegative staphylococci. The relative
proportions of each of these vary
from individual to individual and
none of them are pathogens. The
odor is known to result from bacterial decomposition of apocrine secretions. This fluid is somewhat sticky
and thus adheres to the hair growing
out of the axillary area. This hair also
provides the bacteria with a greater
surface area on which to grow and
come in contact with apocrine secretions.

There are three methods for reducing underarm odor with drugs, based upon what is known about this condition. These include inhibiting bacterial growth, reducing apocrine secretions, and removing all sweat secretions from the skin as quickly as possible. The primary means, needless to say, is this third alternative, achieved by regular, effective washing of the area. Many experts (and millions of "non-experts") believe that shaving the hair from the underarms (a practice popular with women) is helpful in preventing axillary odor. Although this is usually done more for cosmetic reasons, it not only reduces the ability of bacteria to produce odor, it also enhances the detergent and mechanical action of soap when the area is washed.

Decreasing wetness by reducing sweat production is another effective method for reducing underarm odor. This occurs because the three factors that enhance bacterial growth are the nutrients in apocrine secretions, the warm temperature, and the wetness supplied by the water in both forms of sweat. Since the principle source of wetness in the underarm area is eccrine sweat, limiting secretions by these glands will reduce odor. Antiperspirants accomplish this. It should also be noted that those agents cleared by the FDA advisory panel that reviewed them as being safe and effective, were felt to have a direct bacterial action on organisms with which they came in contact.

Do Antiperspirants Really Work?

Currently there are three proposed theories that are purported to explain the mechanism of action of antiperspirants. None has been proven conclusively. One holds that metallic ions in the chemicals bind with anions in the keratin issue and form a functional closure of the sweat gland duct. This, then, reportedly causes an intraluminal pressure head which stops glandular secretion via a feedback mechanism.

Another theory suggests that aluminum and zirconium salts alter the permeability of water within the sweat duct and cause it to flow into the tissue below the epithelial skin. This, then, is taken back up in the blood instead of being deposited on the surface.

The third theory is that the metallic ions decrease sweating by interfering with acetylcholine-induced nerve stimulation of the gland. The proposed mechanism is that the metallic ions in the antiperspirant have a direct effect on acetycholinesterase (the enzyme that metabolizes acetylcholine).

However, the panel that reviewed the antiperspirant drugs was not convinced that they exert sufficient "anti-wetness" action to be the only mechanism of action. Its members felt that even though the resulting dryness is less suitable for bacterial growth, the currently used OTC agents (especially the aluminum chlorohydrates and aluminum chloride) possess some antibacterial action in their own right. This means that, in the panel's view, an effective antiperspirant is also an effective deodorant whether or not it has a "perfumy" odor.

Remember that the odor associated with underarm perspiration is due to bacterial breakdown of apocrine secretions. No OTC product is known to cause an effect on apocrine sweat production. Sweat produced by the apocrine glands enhances bacterial growth and the formation/ evaporation of odor. Eccrine sweat production is a normal part of the biological function that helps regulate body temperature and electrolyte balance. These glands are located over the entire body (estimated to exceed three million); they become active under thermal stress. The eccrine sweat then evaporates from most areas of the skin and cools the blood circulating through the skin and, therefore, the body itself.

The eccrine glands in the underarm area are further unique in that they alone are stimulated by emo tional stress. This adds to odor pro duction. The net result is that, since the underarms are not important in overall regulation of body tempera ture, their sweat production can be inhibited by antiperspirants withou jeopardizing body hemostasis Therefore, they are safe and effective for OTC use as antiperspirants. Table 2 lists those products that have been ruled by the FDA's advisory panel to be safe and effective. The basic com ponents are aluminum chloride, alu minum chlorohydrates, and alumi num zirconium chlorohydrates.

TABLE 2 Safe and Effective OTC Antiperspiran Drug Ingredients*

Aluminum chlorohydrates:

Aluminum dichlorohydrate
Aluminum sesquichlorohydrate
Aluminum chlorohydrex PG
Aluminum dichlorohydrex PG
Aluminum sesquichlorohydrex PG
Aluminum chlorohydrex PEG
Aluminum dichlorohydrex PEG
Aluminum sesquichlorohydrex PEG

Aluminum chloride (aqueous solutions up to 15%)

Aluminum sulfate

(buffered with aluminum lactate)

Aluminum zirconium chlorohydrates:
Aluminum zirconium
trichlorohydrate
Aluminum zirconium
tetrachlorohydrate
Aluminum zirconium

pentachlorohydrate Aluminum zirconium octachlorohydrate

Aluminum zirconium trichlorohydr GLY

Aluminum zirconium tetrachlorohydrex GLY Aluminum zirconium pentachlorohydrex GLY Aluminum zirconium octachlorohydrex GLY

PG = Propylene glycol complex PEG = Polyethylene glycol complex GLY = Glycine complex

*as determined by an FDA advisory panel

Aluminum chlorohydrates of composed of nine different sof forms. They vary in the ratio of alminum ions to chloride ions with

the molecule, and whether they are complexed with propylene glycol or polyethylene glycol. The latter two substances (the glycols) increase the alcoholic stability of the salts and enhance their ability to form the various vehicles used for commercial antiperspirants. They are, however, considered to be approximately equal to each other in effectiveness.

Aluminum zirconium chlorohydrates are somewhat similar to the aluminum chlorohydrates in that the basic differences between the members of the group are their ratio of aluminum to zirconium to chloride atoms, and whether or not they are complexed with glycine. Glycine enhances their formulation properties.

When aluminum chloride hydrolyzes in solution, it forms several compounds including oxychloride and free hydrogen ions. These ions lower the pH substantially and solutions greater than 15% are not considered to be safe for OTC use. Aluminum chloride reduces sweating to a significantly greater degree than do the other antiperspirants, but it also has a greater tendency to irritate the skin.

While buffered aluminum sulfate is considered to be a safe OTC antiperspirant, the unbuffered form (cake alum) is not. The unbuffered form produces a high degree of skin irritation. Adding sodium aluminum lactate to the product buffers the solution and significantly decreases the irritation caused by aluminum sulfate itself. Another complex, potassium aluminum sulfate (i.e., medicinal alum), is known to possess styptic and astringent activities, but it has never been clinically tested for its antiperspirant activity.

The panel concluded that two other agents were definitely unsafe for OTC use. They are zirconiumcontaining aerosols and alcoholic soutions of aluminum chloride. As stated earlier, some zirconiumcontaining formulations are considered to be safe and effective, but not he aerosols. The problems with hem stem back to evidence gathered decade ago that chronic inhalation of zirconium-containing aerosol products might produce abnormal issue growth in the lungs. They were removed from the market and will not be allowed back until adequate testing is done. Aluminum chloride in alcoholic solutions is barred from OTC sale because data relating to its use have resulted from prescription use under medical supervision. The FDA could find no evidence that it is safe for self-use via the more open OTC market.

Consumer Counseling

Since there are no significant differences between the various ingredients, a major determinant in choosing an antiperspirant is whether or not a particular product irritates the skin. Good advice is to use "whatever works for you." Another factor is the product smell. However, covering one odor with another is not a substitute for proper hygiene.

Most often, repeated application of the antiperspirant is needed before significant wetness reduction is seen. Also, the underarm area should be dry before application and be allowed to dry afterwards. Applying an antiperspirant when one is sweating prevents the agent from penetrating into the sweat gland ducts. Allowing the area to dry after application, before putting on clothing, will lessen the chance of the product hydrolyzing to hydrochloric acid which induces skin irritation. Irritation is also reduced by not applying antiperspirants to abraded or freshly shaved skin. Since all of us are biochemically different, if one product fails to do the job, another one with a different combination of ingredients may do fine.

Feminine Hygiene

The question of whether or not to use douche products and feminine deodorant sprays stirs up a great deal of controversy. Some gynecological experts question the use of the latter agents, stating that they may cause more harm than good to sensitive vaginal tissue. Douching has both proponents and opponents. Some experts believe that proper douching enhances the health of vaginal tissue, and that proper cleansing of the perianal area is imperative to prevent vaginitis. Others argue that the vagina is quite capable of keeping itself clean and that adequate washing will prevent the spread of organisms from the anus to vagina.

Several factors contribute to the proper function and health of the vaginal tract. These include the thickness of the lining, pH, various secretions, and the bacterial flora.

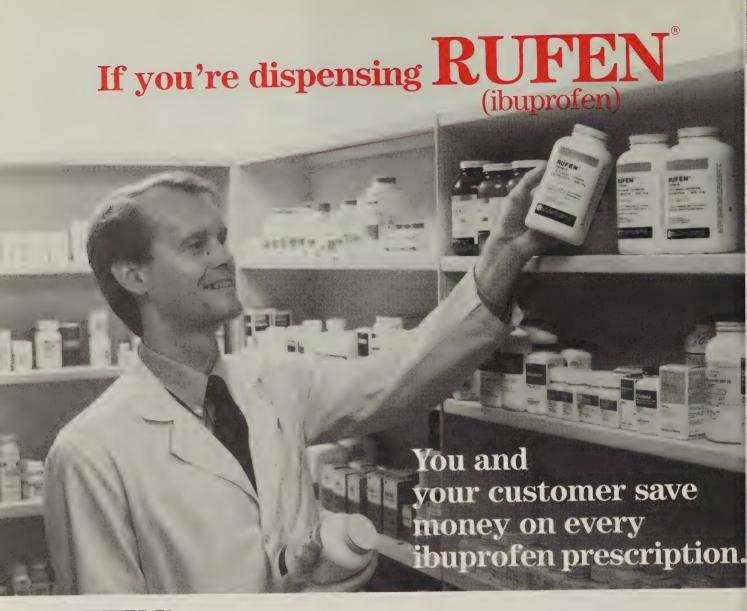
The thickness and consistency of the vaginal epithelial lining is determined by the level of estrogens in the body. During the years following menses but before menopause, estrogen blood levels are high and vaginal tissue cell height is greatest. The chance for pathogenic invasion of the vagina at this time is less likely than before or after menstruation.

Two other factors, vaginal pH and bacterial flora, are interrelated. Again, there are major differences in these during the childbearing years. Before menses begins and after menopause occurs, the pH of the vaginal tract is somewhat alkaline. During the childbearing years, the pH averages between 3.5 and 4.2 with a range of 3 to 6. It is known that keeping the vaginal tract acidic aids the endogenous nonpathogenic bacteria/ flora to inhibit infection from occurring. Whenever the pH becomes alkaline (as in pregnancy and during oral contraceptive use) vaginal infections are more likely to occur.

A variety of secretions are produced in the vaginal tract that cleanse and lubricate. They include secretions from sebaceous, apocrine, and eccrine glands (covered earlier), as well as from other special glands. In themselves, they have no odor, but if they remain on the external surface of the vagina, bacterial decomposition can and will produce odor. Two organisms that are especially implicated in odor production are Trichomonas and Gardnerella (previously called Haemophilus) vaginale. They also cause inflammation as does another pathogen — the yeast Candida albicans.

When douching is indicated for medical purposes, the most common reasons are to alleviate itching or burning of the external vagina (vulvar pruritis), to remove excessive vaginal discharge (leukorrhea), to modify the infectious vaginitis conditions mentioned above, and to treat non-specific vaginitis (i.e., the cause is unknown).

Much of the douching controversy centers on the fact that there are no pain and itching symptoms until the



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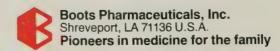
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inflammation has spread to the external genitalia. Therefore, a considerable cadre of gynecologists believe that the question of whether to douche or not is best answered by consultation and discussion between physician and patient rather than by heeding the advertisements in ladies' magazines.

Needless to say, none of the above mentioned conditions is amenable to self-medication. However, there is a move to make anti-candidal agents (e.g., nystatin) available OTC for women who have had candidiasis (moniliasis), are able to self-diagnose the condition, and can begin treatment while waiting to see the physician, who will determine whether other therapy is needed later.

This has been suggested by the FDA Advisory Panel on OTC Antifungal Drugs, and representatives of OTC manufacturing companies agree. At the time of writing this lesson, however, FDA has not accepted the shift of anti-candidal drugs to OTC status. While miconazole and haloprogin were granted OTC status, their manufacturers can promote them to the public for treatment of ringworm but not candidal infections.

While not taking sides in the argument of whether it is beneficial to douche, we should review the ingre-

TABLE 3 **Representative OTC Douche Products**

Product	Ingredients
Betadine	Povidone-iodine
Bo-Car-Al	Boric acid, eucalyptus, menthol, methyl salicylate, phenol, potassium aluminum sulfate, thymol
Demure	Benzethonium chloride
Dismiss	Cetearyl octate, citric acid
Femidine	Povidone-iodine
Gentle Spring	Sodium lauryl sulfate
Jeneen	Lactic acid, octoxynol
Massengill Disposable	Cetylpyridinium chloride, lactic acid, octoxynol
Massengill Liquid	Lactic acid, octoxynol
Massengill Powder	Ammonium aluminum sulfate, methyl salicylate, phenol, thymol
Massengill Medicated	Povidone-iodine
Massengill Vinegar	Citric acid, vinegar
New Freshness	Vinegar
Nylmerate II	Acetic acid, boric acid, nonoxynol
Operand	Povidone-iodine
Phenithyn	Benzethonium chloride
PMC	Ammonium aluminum sulfate, eucalyptus, menthol, phenol, thymol
Povi-Douche	Povidone-iodine
Summer's Eve	Citric acid
Summer's Eve Medicated	Potassium sorbate
Summer's Eve Vinegar	Sorbic acid, vinegar
Stomaseptine	Eucalyptol, menthol, thymol
Trichotine	Sodium lauryl sulfate
Triva	Alkyaryl sulfonate, oxyquinoline
V.A.	Boric acid, oxyquinoline, potassium aluminum sulfate, zinc sulfate
Vagesic	Docusate, polyoxyethylene nonyl phenol
77 1.	

Benzalkonium chloride, menthol, thymol

TABLE 4 Ingradients in OTC Daugha Braduct

Ingredients in OTC Douche Products			
Ingredient	Claimed Action		
Acetic acid	Acidifier		
Alkyaryl Sulfonate	Surfactant		
Ammonium	Astringent		
aluminum sulfate			
Benzalkonium	Surfactant*		
chloride			
Benzethonium	Surfactant*		
chloride			
Boric Acid	Acidifier*		
Cetearyl octate	Surfactant		
Cetylpyridinium	Surfactant*		
chloride			
Citric acid	Acidifier		
Eucalyptus	Analgesic		
Lactic acid	Acidifier		
Menthol	Analgesic		
Methylbenzethonium	Surfactant*		
chloride			
Methylsalicylate	Analgesic		
Nonoxynol	Sufactant		
Octoxynol	Surfactant		
Oxyquinoline	Antimicrobial		
Phenol	Analgesic*		
Polyoxyethylene	Surfactant		
nonyl phenol			
Potassium aluminum sulfate	Astringent		
Potassium sorbate	Antimicrobial		
Povidone-iodine	Antimicrobial		
Sodium laryl sulfate	Surfactant		
Sorbic acid	Antimicrobial		
Thymol	Analgesic*		
Vinegar	Acidifier		
Zinc sulfate	Astringent		
- DITTO GUITATO	ristringent		

^{*}also claimed to have antimicrobial action

dients contained in OTC products, and discuss how they act. Most OTC douche products consist of one or more of the following agents: acidifiers, antimicrobial agents, astringents, counterirritants, and/or surfactants (see Table 4). At this time, none of these has been proven effective for its intended use.

The acidifiers contained in OTC douche products include acetic acid (vinegar), boric acid, citric acid, and lactic acid. While commercial products are more convenient and expensive than homemade vinegar solutions, there is no evidence that any of them is more effective than a solution made from two tablespoons of vinegar in a quart of warm tap water. Acidifiers are used to lower an elevated vaginal pH to a more infectiveresistant acidic pH.

Antimicrobials include the quaternary ammonium compounds (QAC's), benzalkonium chloride,

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benzethonium chloride, cetylpyridinium chloride, and methylbenzethonium chloride. These agents also serve as surfactants. Other antimicrobials used are oxyquinoline, phenylmercuric nitrate, povidoneiodine, and potassium sorbate/sorbic acid. Boric acid is also claimed to have antimicrobial activity. However, most of these agents are present as preservatives, rather than in concentrations likely to be antimicrobial. None has been proven to be an effective antimicrobial for this use.

Astringents are purported to reduce local edema, inflammation, and discharge. Those items claimed

to exert this action when included in douche preparations are ammonium and potassium aluminum sulfate (alums) and zinc sulfate. These agents exert beneficial effects on skin and other mucous membranes so it can be assumed they will do the same on vaginal tissue.

Eucalyptol, menthol, methyl salicylate, phenol, and thymol are counterirritants which are added to the products to provide anesthetic, antipruritic, and antiseptic effects. Evidence of these effects are lacking. Many feel that, at the concentrations needed to provide counterirritant effects, the products would be too irri-

tating to the sensitive membranes of the vaginal tract. In reality, at the strength present in OTC douche products, they are believed to provide a soothing, "refreshing" deodorant effect.

Surfactants such as docusate salts (previously called dioctyl sulfosuccinates), nonoxynol, octoxynol, and sodium lauryl sulfate are included to decrease surface tension and facilitate the spread of the douche solution over the mucosa of the vaginal tract. They are all effective for this purpose as are the quarternary ammonium compounds.

LETTERS



Dear David.

I am writing to you today in behalf of the annual seminar committee of the Maryland Society of Hospital Pharmacists. As you may know M.S.H.P. is having their annual seminar this year at Host Farm Resort in Lancaster, Pennsylvania. The seminar is to be held June 14–16, 1985

We would like to have our seminar mentioned in your publications. So that we can have a good turnout, learn a lot, and have some fun also in the beautiful Amish-Pennsylvania countryside.

Specific speakers and their topics are still being confirmed and brochures and more information will be ready soon.

Thank you for your help in this matter.

Please see following information:

MEETING: ANNUAL SEMINAR

SPONSOR: MSHP

DATE: June 14–16, 1985

PLACE: HOST FARM RESORT, LANCASTER,

PA.

CONTACT: KATHRYN HIGBEE, Pharmacy Dept.,

St. Agnes Hospital, 900 Caton Avenue, Baltimore, Maryland 21229 (301)368-

7822

Sincerely,

Dear Dave:

Recently and in the past, pharmacists who refilled prescriptions without authority often claim that they received authority from someone working in the physician's office. Many times, in trying to verify this information, we have found that the physician and the members of the staff deny any knowledge of giving authorization to the pharmacist.

To prevent the situation from occurring, the Maryland Board of Pharmacy strongly recommends that any pharmacist who receives prescription information on the telephone should record the name of the individual to whom he or she is speaking. This information would verify the fact that authorization was received directly from the prescriber's office.

Sincerely, Paul Freiman, P.D. Secretary

SUN SAND C.E

Register now for the 1985 MPhA annual Convention! June 23–27, 1985 at the Carousel Hotel in Ocean City Maryland.

A Joint Convention with the Delaware Society of Pharmacists. Largest Exhibit Program Ever. Quality Continuing Education Programs. More events than ever before. Call the MPhA Office for Registration forms at (301) 727-0746

THIS AND THAT ABOUT PHARMACY

by Leon Weiner, P.D.

Spotlight on MORRIS H. BORTNICK

This gentleman comes from a large well known family in the Washington, DC area. All of the people who have worked closely with him have used fine adjectives to describe him during his 24 years of service with Giant Food and Pharmacies, Inc. Morris H. Bortnick, the Senior Vice President, Professional Services, decided to take early retirement and move to sunny Florida in the last month of 1984.

Morris graduated from George Washington University with a BS degree in Pharmacy in 1941. During World War II, he was attached to the Medical Corps, US Engineers, North Atlantic Division and he was instrumental in opening and operating US Engineer base hospitals in the North Atlantic and Central America areas. In 1945-46, he was the medical supply officer for United Nations Relief and Rehabilitation Association and his basic responsibility was maintaining charge of all medical supplies and drugs for the Balkan countries. From 1947 to 1952, Morris acted as manager of two pharmacies in Washington, DC. In May 1952, he bought a large independent pharmacy which he operated until August 1960. His big break came in February 1962 when he went to work with Giant Food and Pharmacies, Inc. and eventually worked his way up the ladder to Senior Vice President, Professional Services.



Even though Morris did not graduate from the University of Maryland, School of Pharmacy, he was honored there by a group of Giant pharmacies who were graduates of that school. Other honors that Dr. Bortnick has received are:

Meritorious Public Service Award, DC Government— June 1961

E. R. Squibb, President's Award—1959Pharmacist of the Year Award, 1959 DC Pharmaceutical Association

In addition, Morris was the President, DC Board of Pharmacy from 1957 to 1961 and the President, DC Pharmaceutical Association in 1959. He is a member of many pharmacy groups including the American Pharmaceutical Association, Maryland Pharmaceutical Association, and Prince George's-Montgomery County Pharmaceutical Association.

We all up in cold, icy Maryland hope that Morris and his lovely wife, Helen, have a long enjoyable stay in Florida and that they do come back once in a while to visit us.

CONGRATULATIONS TO:

- Madeline Feinberg, P.D., UofMD Pharmacy 1979.
 Ms. Feinberg will become President of the Maryland Pharmaceutical Association in June 1985. She is the first woman in history to assume that position. Nobody doubts that she will do a good job since she is such an active person. Madeline is a School of Pharmacy clinical professor, Director of the Elder Health Program and a community pharmacist.
- 2. Berry Means, P.D., of Fallston, MD, has become the new Pharmacy Director at Greater Baltimore Medical Center. Before that for four years, he was Associate Director of the pharmacy at St. Joseph Hospital, and prior to that, he was staff pharmacist, drug information pharmacist, and associate director of the pharmacy at Johns Hopkins Hospital.
- Marvin L. Oed, P.D., UofMD Pharmacy 1956. Marvin Oed, of Rosedale, recently won a grant from the National Association of Retail Druggist Foundation. His project involves improving diabetic education in pharmacies. Besides being the owner of

two Medicine Shoppes in Baltimore County, Marvin is the Director of the Professional Experience Program (PEP) at the University of Maryland, School of Pharmacy.

4. William Tabak, P.D., UofMD Pharmacy 1961. His daughter, Nancy S. Tabak, was recently selected President of the Board of Governors at Springfield College in Massachusetts. Bill is a pharmacist at Rite Aid Drug Stores in the Baltimore area after being with Read Drug and Chemical Company for many years.

RECENT PHARMACY DEATHS

Jacob L. Kronthal, P.D., died February 11, 1985. Graduated from UofMD Pharmacy 1924. Former owner of Kay's Pharmacy, 2444 E. Biddle Street in Baltimore.

Antionette Malanowski Lauten, P.D., died January 20, 1985, age 48. Graduated from UofMD Pharmacy 1959. Worked for Rite Aid Drug Company in Baltimore.

Herbert Wienner, P.D., died February 9, 1985, age 51. Graduated from Philadelphia College of Pharmacy in 1955. Former owner of Park Avenue Pharmacy in Baltimore. Worked for Revco Drug Company in recent years.



Tuesday, October 30, 1984 was a big day in the life of pharmacist Morton Scherr and his brother, Len. It was when the new Marlyn Medical Center in Essex was dedicated with a ribbon cutting ceremony. Dr. Scherr and his brother are the co-developers of this project in cooperation with Charles H. Steffey, Inc. Morton is also the owner-proprietor of Marlyn Pharmacy, anchor tenant in the \$2 million project. Some of the local dignitaries who participated in the opening ceremony were Baltimore County Executive Donald P. Hutchinson, County Councilman Norman Lauenstein, Senator Dennis Rasmussen, and Delegates Michael Collins, Terry Connelly, and Michael Weir. Joseph Meyerhoff,



Those of us who have been in the health care field for a number of years know that pharmacy has changed more during the past decade than it has since its inception as a profession some ten centuries ago.

As we look forward to the twenty-first century, we realize that this rapid change has become a way of life, not only in our profession, but in almost every daily activity with which we are involved.

In my pre-college days, friends and peers often chose pharmacy as a career because a father or close relative was a pharmacist and the family considered it a prestigious profession to enter. To a degree, the profession was somewhat self-perpetuating.

Lately, it seems, things have made a complete turnaround. Statistics show that pharmacy school enrollments are on the decline. Computer science and engineering are coming to the fore—the top choice for many of today's graduates. Although pharmacy is still a very highly-respected profession, young people today are pursuing other interests and are often not as interested in careers in health care as were previous generations.

Because of our concern about the effects of this trend on the profession, A. H. Robins has produced a videotape entitled, *Rx for the Future*, which is being made available to pharmacy organizations across the country for their use in acquainting practitioners with the problem—enlisting their support in helping to change it.

The videotape is informative and low key, showing pharmacists how to talk to high school and college students about pharmacy—and how to interest them in making pharmacy their career. The tape simulates two students talking with a community pharmacist, asking questions, telling him their feelings about the profession—and ultimately deciding that pharmacy is the profession for them.

Inquiries regarding the availability of the film for local showings should be made to any college of pharmacy or your state pharmaceutical association.

Pharmacy is *our* profession, and A. H. Robins feels that it is up to all of us to keep it strong and viable for coming generations.

A-H-ROBINS

A. H. Robins Company
Richmond, Virginia 23220

who provided financing for the project, also participated in the festivities. For Morty Scherr, UofMD Pharmacy 1953, it is a start of a new adventure and the end of several years struggling in a temporary double trailer pharmacy.

The Medicine Shoppe, 6501 Reistertown Road in northwest Baltimore, finally opened on Monday, December 17, 1984, after an unexpected delay of six weeks. The new formal opening was held on January 7, 1985. It was great to see a big smile on the face of Steven Herlich, the owner of the pharmacy. Steve, a UofMD Pharmacy 1982 graduate, formerly worked at Thrift Drug Stores and Peoples Drug Stores. We wish him the best of luck on his new enterprise.



Raymond A. Wisniewski





PHARMACY CHANGES—January 1985

The following are new pharmacies in Maryland:

Broadneck Pharmacy 269 Peninsula Farm Road Arnold, MD 21012

The Medicine Shoppe 5507A Ritchie Highway Brooklyn Park, MD 21225

Revco Drug #2730 Rt. 13 and Mt. Vernon Road Princess Anne, MD 21853

Revco Drug #2733 661 Old Mill Road Millersville, MD 21108

Safeway Pharmacy 3400 Annapolis Road Baltimore, MD 21227

Weis Pharmacy #121 18451 Mateney Road Germantown, MD 20874

PHARMACIST IN THE NEWS

Above to the left is a picture of Raymond A. Wisniewski as he appeared in his University of Maryland Pharmacy Yearbook of 1973. To the right, 12 years later, Ray is with his two handsome sons as he poses with the VCR that he won at a recent drawing at Safeway during the recent Market Square Merchants celebration of the Market Square Shopping Center's 10th anniversary in Shrewsbury, PA. The son on the left being held by Ray is Gregory and the other is Christopher. Ray, who lives in Shrewsbury, crosses the Maryland State line and heads south to Baltimore where he is presently working as a pharmacist at the Maryland Penitentiary. Prior to that, he worked for the Rite Aid Corporation.

Change of ownership

Old: New: Charles Rossberg Jr. Pharmacy Rossberg Professional Pharmacy

2526 Washington Blvd.

Baltimore, Maryland 21230

New Owner: RoseZarow

SALARY AND BENEFITS SURVEY

Kathleen Gauthier David Miller Student Externs, MPhA

In compiling the results from the 1984 MPhA Salary and Benefits Survey of pharmacists in Maryland, we have separated the results into three distinct categories, full time employees, part time employees and pharmacy owners, to more clearly demonstrate the breakdown the differences between salaries and job satisfaction. Also, comparisions were drawn between the Maryland results and the soon-to-be published *Drug Topics* nationwide annual salary and job satisfaction survey. Some surprising discrepancies and changes were noted in this year's survey!

TABLE 1
Overall Respondent Profile

OWNERS	# RESPONDING	PERCENT OF TOTAL
Partnership	2	0.98%
Sole	10	4.92%
Corporation	38	18.73%
Store/Pharmacy Manager	30	14.78%
Chief Hosp. Pharmacist STAFF PHARMACIST	5	2.47%
Independent	46	22.66%
Chain	32	15.76%
Hospital	15	7.39%
Sales Reps.	2	0.98%
Other (govt., consultants, retired)	23	11.33%
TOTAL	203	99.98%

The Maryland questionnaires were mailed to each of the 1100 members of the Association in December; 203 surveys were returned giving a response rate of 18.55%—a decrease of 5% from the previous survey. A profile of the respondents appears in Table One.

Full time employees salary figures were broken down into two categories: salary by site of employment and salary by age (Table 2A and 2B). Overall, average salaries have increased 8.89% for males and only 3.97% for females. Among staff pharmacists, chain drug stores lead the way in salary figures for both males and females, with independents following close behind and hospitals paying about 25% less than community based pharmacies. As could be expected, managers and chief hospital pharmacists had greater average salaries than their staff employees. Benefits provided to pharmacists, as in past years, were so diverse and so variable as to employee vs. employer contribution that meaningful statistics and overall generalizations could not be drawn.

The old myth that pharmacists start out making good salaries but have low increases seems to be borne out by the survey results (Table 2B). New graduates, those in the 21 to 25 year age group, are making only about \$300.00 less than pharmacists 10 years their senior. Higher age groups tend to show an increase, primarily due to the larger number of managers and supervisors in this category. At the end of the age scale, salaries begin to drop off.

TABLE 2A
Full Time Employment
Salary by Work Site

	MALE		FEMALE	
WORK SITE	AVE. SALARY	RESPONDENTS	AVE. SALARY	RESPONDENTS
Staff Pharmacist:				
Independent	31,243.86	22	28,128.00	5
Chain	34,990.00	20	31,944.00	9
Hospital	26,670.00	10	28.075.00	4
Manager			,	·
(Pharmacy/Store)	39,330.70	26	30,833.00	3
Sales Represent.	30,000.00	1	26,000.00	1
Chief Hospital				
Pharmacist	43,850.00	4	32,000.00	1
Other(*)	46,650.00	6	31,330.00	3
(Govt./Executives/ Consultants)				
AVERAGE SALARY:	\$34,347.31		\$29,496.67	

^(*) Category not used to calculate average salary.

TABLE 2B Salary by Age

AVERAGE YEARLY SALARY # RESPONDENTS 21-25 \$32,558.33 12			
21-25 \$32,338.30	AGE		# RESPONDENTS
26-30 32,928.84 32 31-35 32,833.00 12 36-40 35,140.00 21 41-45 43,300.00 7 46-50 41,875.00 6 51-55 39,700.00 10 56-60 35,430.75 13 61-65 28,166.00 3 66-70 18,000.00 1	26-30 31-35 36-40 41-45 46-50 51-55 56-60 61-65	32,928.84 32,833.00 35,140.00 43,300.00 41,875.00 39,700.00 35,430.75 28,166.00	32 12 21 7 6 10

Job satisfaction questions provided some surprising changes over previous year's answers (Table 2C). All areas declined with the biggest change being in the work atmosphere/morale category. In the previous survey, 34.44% rated their work atmosphere as excellent, while only 3.43% considered it poor. This year, the excellent category dropped to 18.33% and the fair and poor categories showed marked increases. Since previous surveys included both owners and employees in job opinion results, splitting the two apart might have uncovered a dissatisfaction that has existed for awhile rather than a new trend development.

Part time employees comprised 12.84% of the total respondents (Table 3A). Three-quarters of part timers worked in independent pharmacies at an average of 16.7 hours per week. There seemed to be little correlation between wages paid and age groupings (Table 3B); \$13.54 per hour was the average wage—an increase of \$2.18 (19.2%) over 1982 figures. Generally, job satisfaction was higher for part time employees than for full timers (Table 3C).

Pharmacy owners reported an average salary of \$45,583.00, a 28.6% increase over 1982 (Table 4A). Curiously, average salaries compared to years of ownership showed no correlation, although this may be indicative of more experienced owners using tax shelters, profit sharing, etc. to help alleviate their personal tax burden. New owners, those in the 0 to 5 year category, reported that they drew salaries greater than owners who had been in business for ten to twenty years. Across the board, starting salaries for employee pharmacists were consistent at around twenty five thousand dollars per year (Table 4B).

Miscellaneous information generated, (Table 4C), provides a good composite of the average pharmacy

TABLE 3A
Part Time Employment

RESPONDENTS Male Female Total	15 11 26	(58%) (42%)
WORK SITE Staff Pharmacist Independent Chain Hospital Manager: Unspecified:	19	(73%) (12%) (4%) (4%) (8%)
AVERAGE HOUF 16.7 hours per v		ED

TABLE 3B Salary by Age

AGE	AVERAGE HOURLY WAGE	# RESPONDENTS
21-25 26-30 31-35 36-40 41-45 46-50 51-55 56-60 61-65 66-70 70-75 76-80	12.00 14.10 15.17 13.60 14.00 	1 5 3 3 1 0 1 0 3 1 5 3
	HOURLY WAGE	

owner responding to the survey. Incorporated pharmacies were most common, leading partnerships and sole-proprietorships by correlates well with the gross income range per store as reported in the 1984 Lilly Digest. Almost 60% of owners indicated that their stores were computerized, a trend that we expect to see increase in future reports. Average salary paid to relief pharmacists per day was consistent with the average reported by part time employee pharmacists; however, full time employee pharmacists indicated that they earned almost \$2,000 more than owners reported paying them!

One of the most striking differences between the Maryland results and those of the *Drug Topics* survey was that the nationwide average salary for hospital staff pharmacist is \$31,758.00 while in Maryland this average

TABLE 2C
Job Opinions

	EXCELLENT	GOOD	FAIR	POOR
Employee/Supervisor Relations Employee/Employer Relations Physical Working Conditions Work Atmosphere (Morale) Store Location	38.39%	41.96%	15.18%	4.46%
	32.48%	49.57%	12.82%	4.27%
	22.88%	53.38%	19.49%	4.23%
	18.33%	45.00%	27.50%	9.16%
	28.30%	47.16%	19.81%	4.71%

TABLE 3C Job Opinions

	EXCELLENT	GOOD	FAIR	POOR
Employee/Supervisor Relations	66.66%	22.22%	0.00%	11.11%
Employee/Employer Relations	56.52%	34.78%	4.34%	4.34%
Physical Working Conditions	26.08%	47.82%	21.73%	4.34%
Work Atmosphere (Morale)	21.74%	60.86%	8.69%	8.69%
Store Location	39.13%	56.52%	0.00%	4.34%

TABLE 4A Owner Information Salary by Years of Ownership

		*
YEARS OWNERSHIP	SALARY	# RESPONDING
0-5	\$43,067.00	9
5-10	56,260.00	10
10-15	38,286.00	7
15-20	40,750.00	4
20-25	54,286.00	7
25-30	33,100.00	5
30 & greater	53,333.00	3
AVERAGE SALARY: \$45,		•

is only \$27,372.50 (13.8% lower). Independents nation-wide made only \$28,030—Maryland independent staff pharmacists are making \$29,680.00 (5.6% higher). Chain staff pharmacists in Maryland were comparable to the average salary nationwide of \$33,233.00. The *Drug Topics* survey will appear in the April and May issues. Watch for it!

TABLE 4B
Salary Paid to Starting Pharmacists (Full Time)

YEARS OWNERSHIP	STARTING SALARY	# RESPONDENTS
0-5	\$25,728.00	7
5-10	25,179.00	10
10-15	25,337.00	6
15-20	28,740.00	4
20-25	25,634.00	7
25-30	25,720.00	4
30 & greater	27,653.00	3
AVERAGE STARTING SA	ALARY PAID: \$25.8	00 00

TABLE 4C
Miscellaneous Information

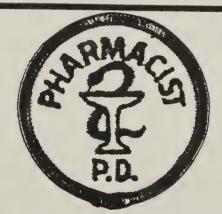
CATEGORY	INFORMATION	# RESPONDENTS
Gross Income/Store	\$724,000	47
Square Footage/Store	2467.5 sq ft	46
Sq. Footage/Pharmacy	535 sq ft	47
Hours worked/week Avg. Salary Paid:	48 hours	49
Technician	\$5.00/hours	29
Pharmacists	\$28,657.00	28
Relief Pharmacist	\$107.00/day	28
Avg. # Employees Computerized	14	28
YES:	59%	29
NO:	41%	20

EDITORIAL COMMENTS

Most respondents did not include comments, but as expected, those who did were mainly dissatisfied with either salary or general working conditions. Many of the comments were related to uninterrupted breaks, inadequate financial advancement, recognition or encouragement based on experience of performance, increased regulation of the profession and the suppression of professional discretion. Here is a sample of some of the written comments:

- —"Hairdressers make more than this"
- —"Pharmacy seems to be slipping away from the pharmacists."
- —"I am plagued by insufficient help and a poor image that my company imparts to consumers, mainly due to emphasis on price, with little regard to service or competence."

Special Note to the lowest paid pharmacist in Washington County and possibly all of Maryland. You were right!!



ACTUAL SIZE

Pharmacist Insignia PATCH NOW AVAILABLE

The new emblem for pharmacists utilizing the "P.D." designation has arrived. Designed to be sewn on dispensing jackets, these new insignia are embroidered in dark blue with a white background, and cost \$1.50 each.

To order, send check or money order for emblems @ \$1.50 each to:

Maryland Pharmaceutical Assn. 650 W. Lombard St. Baltimore, Md. 21201

STADT-APOTHEKE (Town Pharmacy) A Memorable International Visit

by

Dr. Grady Dale, Jr.
Assistant Dean for Student Affairs
University of Maryland School of Pharmacy

When it comes to history, tradition, and progress, the STADT-APOTHEKE in Metzingen, Federal Republic of Germany is in a class by itself. Located in this small town outside Stuttgart, the Stadt-Apotheke has been on the same spot since 1780, and has been owned by the Kleinknecht Family since 1909. They celebrated their 75th Jubilee of ownership this year.

Frieder Kleinknecht, a modest, gracious man, has been a pharmacist for 37 years. He is following in his father's footsteps, serving the pharmacy needs of the 12,000 citizens of Metzingen in the traditional personal manner, and filling 25,000 prescriptions a year. In addition he has been a respected national leader in the upgrading of pharmacy as a profession, and the training of pharmacists in postwar Germany. His interest in the training of students parallels my own. I am currently investigating student training opportunities abroad. Recently I met Harald Skrobligs, a German community pharmacist studying at the Health Research Group in Washington, D.C. He suggested that I meet with Herr Kleinknecht while in Europe on vacation in October.

I visited Herr Kleinknecht at his home in Metzingen on October 13 & 14, 1984. I wanted to explore with him the possibility of an exchange program between pharmacy students in the Federal Republic of Germany and the University of Maryland School of Pharmacy. Although I know little German, Herr Kleinknecht and his son, Helmut, an economist spoke enough English for us to communicate effectively.

Our discussion covered a wide variety of topics relative to pharmacy in our two countries. We talked about similarities and differences; of students, of curriculums in pharmacy schools, of practicum requirements, and of store operations. According to Herr Kleinknecht, pharmacy students in the Federal Republic are generally about 19 to 29 years of age when they begin study. In Germany, space in pharmacy schools is severely limited, and some students must wait several years for admittance. Women are now entering the profession at an increasingly higher rate.

The pharmacy curriculum is set at the national level. Generally it consists of:

- —Two years of studies in chemistry, biology, and physics, after which the students must pass a multiple choice examination.
- —Another year and a half which is devoted to studying pharmaceutical chemistry, biology, pharmaceutical technology, and pharmacology. The student must then pass a combination written and oral examination.
- —One additional year which is spent in a pharmacy practicum. The student must pass an oral examination following completion of the practicum.

After completion of all requirements, a license is then granted by the national government authorizing practice.

Pharmacist Kleinknecht and his father before him have trained pharmacy students at STADT-APOTHEKE for more than half a century. He expressed great interest and enthusiasm in seeing more opportunities extended for students to study abroad. An exchange program already operates within Europe. We agreed that the experience of working and learning in another culture would enhance the professional development of the student.

While I was enjoying hot tea and home made German pastries, he described other aspects of the family's pharmacy business. They operate a small drug manufacturing plant on the premises. I followed on a tour of the two story modern immaculate factory. Herr Kleinknecht showed me the compound room, water purification system, the tablet making and drying machines, and other sophisticated equipment. Ointments, suppositories, and various tablets are made for sale to a national buying unit which purchases and sells from small and large operations. Bayer, Pfizer, Ciba, Merck, and other pharmaceutical manufacturers also do business through this national unit.

The pharmacy itself faces a quiet, sunny street of small shops and clean, narrow sidewalks, scarcely changed by the passage of time. Inside however, everything from the automatic entrance doors to the electronic cash register is state-of-the-art technology. A 10 megabyte Hewlett-Packard computer system provides instant technical and marketing information on virtually every drug available within the entire country. I saw how a small town pharmacy, by using the Hewlett-Packard, orders drugs four times a day and receives delivery within four hours, except for the last evening order which is delivered by 8 o'clock the next morning. The computer gives information on drug storage requirements, expiration dates, and drug interactions. Herr Kleinknecht relies on the computer to find all the uses of a drug, as well as for inventory, pricing, and quality control. He has at his fingertips a comprehensive library of all the up-to-date information needed to operate his business most efficiently.

There are 25,000 pharmacists, and 16,000 pharmacies in the Federal Republic. There are no chain stores, although a family member who is a licensed pharmacist may open his/her own individual pharmacy. Herr Klienknecht's daughter in fact is a pharmacist in Frankfurt. His wife Frau Klienknecht, who completed two years of pharmacy study before rearing seven children, operates the family's "related items" store, which includes merchandise such as cameras, cosmetics co-

lognes, etc., commonly found in the United States "drug store." In Germany, drugs that we commonly call "over the counter" can only be sold in a pharmacy. Even aspirin must be purchased in a pharmacy.

On Monday morning I returned to the pharmacy to take photographs of the daily business routines. I discovered my flash attachment was for my other camera, back home in Baltimore. Herr Kleinknecht rushed out and returned with flash cubes from his wife's store across the parking area. We took pictures of—the congenial staff and customers in the store. After an exchange of cards and a hearty handshake, we said goodbye.

I came away from the visit to Metzingen feeling very positive about student exchange possibilities. I plan to follow up with appropriate contracts to industrial organizations and schools suggested by Herr Kleinknecht, who may become the catalyst for an exchange program between the two countries.

On a personal level, I appreciated the genuine warm reception given to me by the Kleinknecht family. I am convinced that their tradition of service and training is indeed in a class by itself.

"We have much to learn from each other"

Written 16 October 1984 Paris, France

Aspirin and the Elderly

by Gary C. Cupit, Pharm.D.

Older patients are heavy users of aspirin and acetaminophen for relieving the aches and pains that accompany aging. These mild analgesics are equally effective on a milligram-for-milligram basis and are widely regarded a safe. However, the growing concern regarding chronic salicylate intoxication and salicylate interactions with other agents has made acetaminophen a safer choice for most indications in people over 55.

For example, oral anticoagulants, methotrexate, probenecid and sulfinpyrazone can interact with aspirin.

With oral anticoagulants, high doses of aspirin (3–4 g daily) can decrease plasma levels of prothrombin, a protein vital to clotting, but the effect is sometimes seen with doses as low as 2 g daily. Aspirin may also produce displacement of the oral anticoagulant from protein-binding sites, resulting in greater free concentration of anticoagulant in the plasma.

Gastrointestinal Bleeding

Of greater clinical significance is the enhanced gastrointestinal bleeding that can occur in patients taking oral anticoagulants and aspirin in doses as low as 2 g daily due to:

- the enhanced hypoprothrombinemic effects;
- the local effects of aspirin on the gastrointestinal tract;
- the ability of aspirin to impair primary hemostasis.

Methotrexate's margin of safety is small. Aspirin enhances the toxic effect of this anticancer drug by competitively inhibiting the secretion of the drug and displacing it from plasma protein-binding sites. The result of both increases the plasma methotrexate concentration.

Avoid High Doses

High concentrations of aspirin also diminish the uricosuric effect of the gout treatment, probenecid. Lower concentrations do not affect the therapy, so that occasional use of aspirin appears to pose no risk for patients taking probenecid. Sulfinpyrazone's uricosuric action is countered by aspirin doses of 3 g per day or higher.

Harmful Effects

Aspirin is probably used by more people and more often worldwide than any other drug, but its potential for harmful side effects and salicylate intoxication is well documented.

Aspirin can cause gastrointestinal erosion and bleeding. Aging patients suffering from gastrointestinal upset also tend to decrease protein and fat intake because they are difficult to digest. And because of poor diets, older patients may be less able to compensate for blood losses.

Numerous reports document aspirin's effect on bleeding time. It interferes with platelet function, inhibiting the release of platelet factor IV and serotonin. Aspirin also abolishes the secondary phase of platelet aggregation normally induced by epinephrine or optimal levels of adenosine diphosphate (ADP). Hence, patients taking aspirin are at increased risk for bleeding episodes.

In the aging, salicylate poisoning is usually the result of unintentional chronic overdose. Signs and symptoms of mild salicylate poisoning include burning in the mouth, throat or abdomen with slight to moderate hyperpnea lethargy, vomiting, tinnitus, hearing loss or dizziness. These symptoms could be confused with neurologic and other organic problems common in older patients.

Salicylate intoxication is often not diagnosed immediately for many reasons, including failure of patients to volunteer a history of aspirin use and failure of physicians, pharmacists and patients to recognize the spectrum of salicylate-induced neurologic abnormalities. These changes along with other symptoms, difficult breathing or pulmonary edema, unexplained blood chemistry changes, such as ketosis, prolonged bleeding time and acid-base disturbances collectively suggest the diagnosis.

Side effects of acetaminophen in normal doses are rare, but include skin rashes and other allergic manifestations. Acetaminophen seems to have no adverse effect on bleeding time or platelet function.

The major concern with acetaminophen is its hepatotoxicity when taken as an acute, massive overdose. With prompt administration of N-acetylcysteine, morbidity is markedly lowered and fatality is virtually eliminated. In nonfatal cases, complete resolution occurs and the liver returns to structural and functional normality.

The aging, who are frequent self-prescribers of OTC analgesics, aspirin and acetaminophen, also take drugs to treat chronic illnesses associated with aging: arteriosclerosis, arthritis, adult-onset diabetes, chronic obstructive pulmonary disease, cancer and cirrhosis. The choice between aspirin and acetaminophen depends on efficacy, risk for interaction with other medications and the likelihood of minor or severe side effects and potential toxicity in the individual patient. Frequent communication between the pharmacist and the patient can ensure effective and safe medication.

Gary C. Cupit, Pharm.D. is Clinical Associate Professor of Pharmacology in the Department of Pharmacy Practice at the Philadelphia College of Pharmacy and Science.

TAXES

Prior to 1980, the Internal Revenue Code permitted an employee to exclude from income amounts received under an employer's self-insured plan for reimbursement of medical expenses incurred by an employee for the care of himself and his dependents. Small corporations favored these plans, which could discriminate in favor of officers and highly paid employees of the corporation by offering the benefits exclusively to these employees. The reimbursements were deductible to the employer, yet not includable as income to the employee.

Changes in the law were designed to dissuade employers from maintaining self-insured medical reimbursement plans which discriminate in favor of officers, shareholders and highly paid employees. Medical reimbursement plans must now meet nondiscrimination rules similar to those rules for participation applicable to qualified retirement plans such as qualified pension or profit sharing plans. Unlike pension and profit sharing, the benefit to the employees cannot be a percentage of their gross income so that the highly paid employees receive larger reimbursements. However, the plans can be limited to a yearly maximum reimbursement for all employees.

The impact of these nondiscrimination rules is that many plans which discriminated in favor of officers or highly paid employees in the past have been terminated or severely modified.

The Tax Act of 1982 has severely limited the deduction for medical expenses for individuals. Starting in 1983 the law increases the floor for medical expense deductions to five percent of adjusted gross income from three percent and eliminates the separate deduction for half of the premiums paid for health insurance.

These changes in medical expense deductions increase the attractiveness of medical reimbursement plans for all employees. New plans can have the effect of providing tax free salary raises for your employees.

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The Friendly Way to Advertise

by J. Allen Scoggin, Pharm.D., M.P.A. and Quentin M. Srnka, Pharm.D.

Allen Scoggin and Quentin Srnka are Associate Professors, Department of Pharmacy Administration, University of Tennessee College of Pharmacy, Memphis, 38163. Doctors Scoggin and Srnka publish a monthly newsletter (Pharmacy Notes) and two weekly newspaper columns (Pharmacy & Your Health and Vitamin & Nutrition News) that are used by pharmacists in the United States and Canada. Sample copies of each can be obtained at no charge by contacting the authors.

Newsletters provide a unique approach to advertising which has been used by a variety of businesses and organizations for decades. More recently, health professionals—especially community pharmacists—have begun to enjoy the benefits of newsletter publication and distribution. One important benefit is an increase in prescription volume. Pharmacist Neil Maxwell in Pleasant Hill, California, for example, reports a 30% increase in prescription volume following implementation of a newsletter program.

The purpose of this article is to acquaint the pharmacist with the newsletter concept. Specifically, we will examine the objectives of effective advertising messages, consider how newsletters fulfill each of these objectives, and list some of the benefits of newsletter advertising.

Effective Advertising

Effective product or service advertising must (1) attract the *attention* of the consumer, (2) stimulate consumer *interest*, (3) create consumer *desire* to have that product or service, and (4) induce the consumer to *action* to obtain the product or service. If one or more of these is missing—ATTENTION, INTEREST, DESIRE, or ACTION—the advertising message will be rendered ineffective.

Newsletters Attract Attention

We believe newsletters are effective because they do *not* appear to be advertisements—they stand out from the many traditional advertising messages that reach the consumer virtually every hour. A newsletter attracts the consumer's *attention* where other advertising approaches fail because it is personal, contem-

porary, and conversational—definitely the "friendly way to advertise."

People read newsletters when they do not even notice other forms of advertising. An article in a recent issue of an advertising industry journal said it well: "The power of newsletters is no longer a secret known only to a few advertising and PR experts. The magic's in the format . . . the readership quality which a newsletter assumes by its editorial (rather than advertising) approach." (Graphic Arts Monthly, March and June, 1983.)

Newsletters Are Interesting

We continue to see much evidence of the public's fascination with information related to health, drug products, exercise, vitamins, minerals, and nutrition. Bookstore shelves contain more selections on these topics every year while many magazines feature health topics on a regular basis. And there is at least one cable television channel dedicated exclusively to health programming.

A well-designed newsletter containing contemporary health information will stimulate the *interest* of consumers. And the pharmacist is the ideal health professional to provide current and future patrons with such information. Studies have shown that the pharmacist is the most trusted health professional. Consumers want to hear what the pharmacist has to say about health-related topics, and newsletters are an ideal format for providing this information.

Newsletters Create Desire

Pharmacists become prominent when their names and photographs appear on newsletters. They gain ε

THE MARYLAND PHARMACIST

degree of *celebrity status* as newsletter publishers. Does celebrity status or, rather, prominence, help create consumer *desire*? We believe it does. People enjoy being associated with prominent individuals such as well-known politicians, business persons, musicians, and movie stars. In the same manner, consumers enjoy knowing and doing business with prominent pharmacists. Pharmacist Thomas Stone of Miami, Florida says, "When information is in print, people tend to believe it. Publishing a newsletter has promoted me as a health authority. They trust me and my newsletter. Customers recognize me and call me by name."

Newsletters Induce Action

Pharmacist Neil Maxwell says, "I am convinced that obtaining my newsletter is one of the primary reasons patients return to my pharmacy." Yet Neil is not alone in observing significant increases in prescription volume following initiation of a newsletter publication and distribution program. Pharmacist John Liska of Lake Havasu, Arizona has observed a 15% increase in prescription volume *every* year. He says, "Distribution of a newsletter has helped us maintain our prescription volume while some of our competitors have seen reductions."

An increase in prescription volume with a corresponding increase in net profit is certainly the "bottom line" for which many pharmacists look. Because publication and distribution is relatively inexpensive, newsletter use is easily justified on a cost-effectiveness basis. Pharmacist Edward Roth of Washington, D.C. has found that newsletter cost is more than "exceeded by an increase in only a few prescriptions each month." A thousand families can typically be reached each month with newsletters for less than \$100.00. The profit from one new prescription daily will usually offset this modest advertising cost. The profit generated from additional new prescriptions—not to mention refills and sales from nonprescription drugs and other products provides the return on the advertising investment. Yet there are many other benefits to be derived from newsletters that cannot be measured directly in dollars and cents.

Other Newsletter Benefits

Distribution of newsletters in the waiting rooms of physicians and dentists gives the pharmacist a reason to call on their offices weekly or monthly. Pharmacist David Morgan of Hyde Park, Massachusetts says, "I place my newsletter in the waiting rooms of several physicians and dentists as patient education materials. I was surprised to find how quickly they accepted use of my newsletter in their offices." While in the office, the pharmacist can establish and nurture relationships with receptionists, nurses, and prescribers.

TABLE 1 Newsletter Distribution

- 1. Display in prescribers' waiting rooms
- 2. Place in patrons' hands at prescription counter
- 3. Use as a statement insert
- 4. Use as a bag/package stuffer5. Hand out when making public presentations
- Display in area factories, plants, colleges, distribution centers, etc.
- Display in area nurseries, day care centers, senior citizen centers, etc.
- Mail to new community residents or mass mail via postal route or zip code
- 9. Contract with newspaper carriers for delivery with newspaper
- 10. Enclose with all pharmacy correspondence

Newsletters will go places other forms of advertising will not reach (such as prescribers' offices). Pharmacist Jeffery Greenstein of Toronto, Ontario reports, "I have been able to distribute my newsletter in places where other forms of advertising would be unacceptable." Because a newsletter does not appear to be an advertisement, it can be displayed in many public places and distributed via several innovative ways (see Table 1, Newsletter Distribution).

The pharmacist's image is modified favorably when his or her name and photograph appear on a newsletter. And when the pharmacist provides health information, patrons tend to ask more questions and rely on the pharmacist's advice. In this regard, Pharmacist Don Vecchio of Wheat Ridge, Colorado indicates that, "Newsletter distribution has helped my customers to see me as a health professional and not just a business person—it lets customers know that I am willing to answer their questions. They now ask more questions about their prescriptions and selection of OTC products."

Well-written newsletters, when properly distributed, are effective in generating *new* business volume. Newsletters are also of value in helping to maintain *existing* volume. Research has demonstrated that the primary reason consumers stop patronizing retail businesses is *employee indifference*. Pharmacist Ryn Moen-Olig of Fargo, North Dakota tells us that, "Including a newsletter with a statement helps customers know that we are concerned with their health—as well as receiving the balance due. It's a nice way of staying in touch."

A Refreshing Change

The concept of newsletters, although an old one, is new to many community pharmacists. Pharmacist Dwaine Green of Lexington, Kentucky has subscribed to "the friendly way to advertise" for several years. He concludes that his newsletter "helps me, helps my practice, and provides my customers with good information on health, medicines, and pharmacy—a refreshing change from traditional advertising approaches. People read my newsletter and think more of me and my practice. What other form of advertising could do this?"

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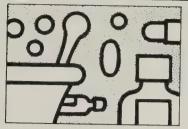
The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

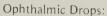


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Things You Should Know FOR YOUR GOOD HEALTH



How to Properly
Instill Your
Eye Drops



- The medication should be at room temperature before it is used.
- The person administering the eye drops should wash his or her hands with soap and water.
- The medication dropper should be pointed tip end down so that the medication does not flow into the rubber bulb. Do not touch the dropper against the eye, eyelid or anything else; the eye drops and dropper must be kept clean.
- Tilt the head slightly backward and toward the side of the eye to be treated, looking at the ceiling.
- Gently pull down the lower lid of the eye to form a pouch.
- Hold the dropper in the opposite hand within one inch of the eye. Instill into the lower eyelid pouch the prescribed number of drops.
- The medication should never be

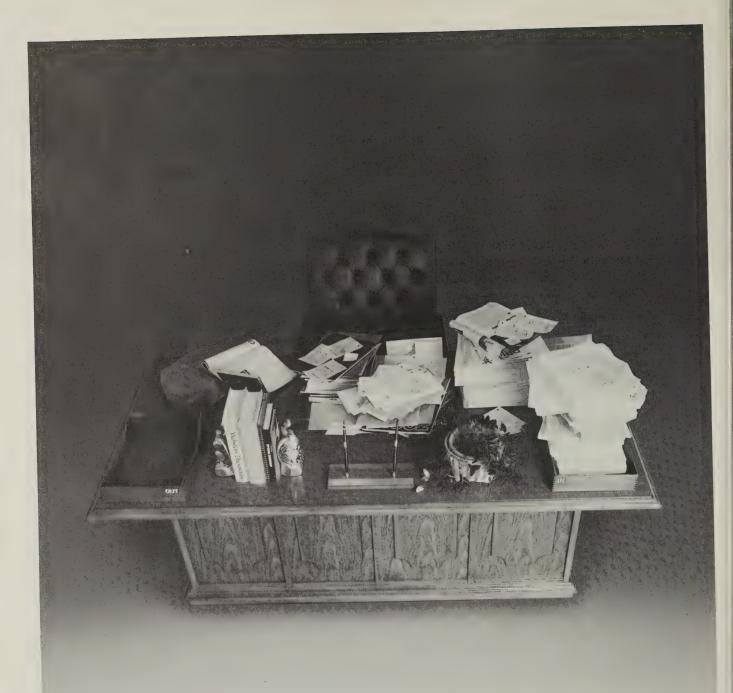
administered directly on the eyeball.

- The eyelids should be closed gently for approximately one to two minutes to prevent escape of the medication and to allow it to be absorbed into the eye.
- Blot excess solution around the eye with a tissue.

Remember:

- If necessary, have someone else administer the eye drops for you.
- Do not use the eye drops if they have changed color, if there are any visible particles in the container, or after the expiration date.
- Never touch the eye or eyelid with the tip of the dropper.
- Keep the bottle tightly closed when not in use.
- The bottle should be properly identified to prevent accidental misuse of the medication.

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Hidden Costs

The direct costs of health care actually account for only 40 percent of the total cost of illness. The remaining 60 percent are indirect costs, such as absenteeism and loss of productivity caused by illness. These are as real economically as the health care expenditures usually associated with illness.

Surprising? Yes. But it should come as no surprise that when the patient gets well faster, both the direct and indirect costs can be reduced.



Eli Lilly and Company Indianapolis, Indiana 46285



The Senior Class of the University of Maryland School of Pharmacy recently visited the A. H. Robins Co. in Richmond Virginia to tour research and manufacturing facilities. Faculty member Marvin Oed accompanied the class.



C. Joseph Stetler received the fourth annual President's Award of the American Society for Pharmacy Law sponsored by Merrell Dow Pharmaceuticals. The Award is presented to an individual who has made a significant contribution to the legal system in relation to the practice of Pharmacy.



Frank McGinity, Jr. (right) is honored by Abbott Sales Representative Bill Kilburn (left) on the occasion of filling the "Two Millionth Prescription" at McGinity Pharmacy on Eastern Ave. in Baltimore.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

DIAZEPAM:

Diazepam (Valium) was given intravenously to patients requiring sedation for either dental or endoscopic procedures. The dose required for an 80 year old patient was 10 mg while 20 year old patients required three times that dosage. The plasma level required for sedation of the older patients was approximately one third of that needed for the younger volunteers. Additional dosage was required in patients who received regular sedation therapy or who were experiencing alcohol intake of greater than 40 grams/day. Increased sensitivity to benzodiazepine derivatives by the brain seems to be responsible for the lower dosage requirement. *Br Med J*, Vol. 6441, #289, p. 351, 1984.

ZINC:

Supplemental zinc preparations have been used with increasing frequency since information has been presented which suggests zinc is useful in conditions such as cancer, growth failure, dermatological problems, etc. New information suggests that excessive intake of zinc (150 mg of elemental zinc taken daily for six weeks) may reduce the activity of the immune system and make the patient more susceptible to infection. Commonly used zinc-containing vitamin preparations, such as Vicon-C, have 50 mg of dried zinc sulfate. As is often the case, moderation is favored with respect to zinc ingestion. *JAMA*, Vol. 252, #11, p. 1443, 1984.

VIP:

Vasoactive intestinal polypeptide (VIP) is being found in various parts of the body and its physiological role is becoming more apparent. VIP is associated with penile impotence as suggested by a study of 28 impotent men. In all cases, the polypeptide was deficient thus strongly suggesting that it plays a role in reproductive physiology. *Lancet*, Vol. II, #8398, p. 315, 1984.

CARDIAC ARREST AND EXERCISE:

A study was designed to determine what effect vigorous exercise would have on primary cardiac arrest. The risk of primary cardiac arrest is transiently increased during vigorous exercise, but is decreased overall with habitual exercise. *N Engl J Med*, Vol. 311, #14, p. 874, 1984.

METHADONE:

Methadone is used to reduce the illegal use of narcotics by addicts in rehabilitation programs, but it has often been found in the plasma of patients found dead of respiratory paralysis. This is especially true if diazepam (Valium) is present. To determine if a special risk is present in patients taking both medications, animal models were given methadone, both acutely and chronically and the influence of diazepam on respiratory function was evaluated. These investigators feel there is a strong, potentially fatal response which can be seen when these two drugs are used concomitantly. They suggest special attention should be given if a patient requires both medications. *J Pharmacol Exp Ther*, Vol. 230, #2, p. 352, 1984.

AMDINOCILLIN:

A new antibiotic, amdinocillin, has been found to be effective against many species of Gram negative bacilli, including E. coli, Salmonella, Shigella, Citrobacter, Enterobacter, Kelbsiella, Proteus and Serratia. Its potency is much greater than that of ampicillin and it has an unusual mechanism of action. Amdinocillin binds specifically to penicillin-binding protein #2, which converts the organism to an abnormal shape which slowly leads to lysis of the cell. This agent, because of its unusual mechanism of action, may be synergistic to other conventional agents such as the beta-lactam penicillins and cephalosporins. *Ann Intern Med*, Vol. 101, #3, p. 389, 1984.

SUDDEN INFANT DEATH SYNDROME:

Sudden infant death syndrome (SIDS) has been said to be due to a variety of causes, yet a common denominator is still being sought. Carotid bodies taken from victims of this phenomenon were examined and were found to contain a ten-fold increase in the concentration of dopamine. Dopamine acts as a respiratory depressant at the carotid site and thus may contribute to death by blunting the ventilatory response to hypoxia. *Lancet*, Vol. II, #8402, p. 535, 1984.

PROBENECID AND FUROSEMIDE:

Furosemide (Lasix) is often used in serious situations to increase renal activity, but it can produce concomitant ototoxicity if levels become excessive. Previous work indicates that high concentrations of oxyger may help protect against this toxicity, but administration is often difficult under these conditions. Experimental animals have been used to demonstrate the protective effect of probenecid (Benemid) against ototoxicity. Animals pretreated with probenecid demonstrates the naturetic effect of the loop diuretic without the toxicity to the ear. Further investigation is warrented. Pharmacol Exp Ther, Vol. 230, #3, p. 1706, 1984.

THEOPHYLLINE OVERDOSES:

Anticipation of the problems associated with drug overdoses can help the clinician prepare for treatment of specific drug toxicities. Theophylline overdoses are not uncommon and several side effects are related to high plasma levels of the xanthine derivative. Toxicity of theophylline includes development of hypokalemia, hyperglycemia, leukocytosis, respiratory alkalosis, hypophosphatemia, and hypomagnesemia. Central nervous system stimulation and restlessness are also seen. *Ann Intern Med*, Vol. 101, #4, p. 457, 1984.

MIGRAINE:

Many clinicians feel migraine headache is a disease caused by allergies to food. A group of nine patients with severe migraine headache refractory to drug therapy were given either a placebo or sodium cromoglycate in a double-blinded study. Patients who received the active drug were protected against symptoms of migraine when challenged by the offending food substance. This data indicates that at least some patients experience migraine headaches because of hypersensitivity to certain foods. *Lancet*, Vol. II, #8405, p. 719, 1984.

SEIZURE CONTROL:

Patients experiencing epileptic seizures were evaluated with respect to drug therapy during their first two years after diagnosis. Investigators concluded that if a patient remained convulsion-free for these first two years, they had a much greater chance of remaining convulsion free. Thus, the first two years of anticonvulsant therapy may be very important in determining the subsequent outcome of drug therapy. *N Engl J Med*, Vol. 311, #15, p. 944, 1984.

DAZOXIBEN:

A potent inhibitor of thromboxane synthetase was administered to patients with Raynaud's phenomenon to determine if thromboxane A-2 might play a role in the pathogensis of this condition. Twenty-four volunteers received dazoxiben orally and their status was monitored. Improvement was negligible suggesting that thromboxane A-2 is not important in Raynaud's disease. Clin Pharmacol Ther, Vol. 36, #3, p. 369, 1984.

ADRENAL ACTIVITY:

Volunteers were given doses of physostigmine to determine what effect this reversible esterase inhibitor night have on adrenal function. The drug increased epinephrine levels in the plasma prompting the investigators to suggest that cholinergic activity in the central nervous system may be partially responsible for regulation of adrenal function. *J Clin Invest*, Vol. 74, #3, p. 1972, 1984.

CALCIUM ANTAGONISM:

Two new calcium antagonists have been used experimentally to reduce symptoms associated with excessive contraction of smooth muscle. Bepridil and cetiedil seem to produce their effects by interacting with calmodulin and preventing activation of the actin/myosin complex. *J Clin Invest*, Vol. 74, #3, p. 812, 1984.

NSAID TOXICITY:

Dermatological reactions to NSAIDs have been reported using a specially designed system. Piroxicam (Feldene) leads the list of offending agents and most dermatological reactions occur in areas exposed to the sun. *JAMA*, Vol. 252, #11, p. 1433, 1984.

PASSIVE CANNABIS SMOKING:

Several volunteers smoked cannabis cigarettes with known concentrations of THC analogs while four volunteers sat passively in the same room. Although the presence of THC could not be detected in the plasma of the non-smokers, urinary metabolites of the active ingredient were identified in the urine for up to six hours after exposure. Forensic toxicologists should note that these metabolites may be found in the urine of those not smoking marijuana, but who have been in contact with those who have. *J Pharm Pharmacol*, Vol. 36, #9, p. 578, 1984.

KETOCONAZOLE:

A group of patients with biopsy-proven prostatic cancer were given doses of ketoconazole (Nizoral) amounting to 400 mg every 8 hours. Ketoconazole greatly reduced the need for analgesics and reduced the levels of testosterone and prostatic acid phosphatase. After six months of ketoconazole therapy, all but one of the fourteen patients in the study were in remission. Lancet, Vol. II, #8400, p. 433, 1984.

ZOMEPIRAC:

Although zomepirac (Zomax) is not generally available for routine clinical use, study of its characteristics continues. Aspirin seems to increase the activity of zomepirac by both displacing it from plasma protein as well as by inhibiting its metabolism by the liver. *J Clin Pharmacol*, Vol. 24, #8 and #9, p. 371, 1984.

H-2 ANTAGONISTS:

Cimetidine (Tagamet) and ranitidine (Zantac) have both been said to reduce hepatic blood flow and thus reduce the elimination of drugs heavily dependent on hepatic conversion for detoxification and excretion. Using a method involving injection of indocyanine green dye as an indicator of hepatic activity, investigators have concluded that chronic use of neither drug is associated with alteration of hepatic blood flow. *J Clin Pharmacol*, Vol. 24, #8 and #9, p. 360, 1984.

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Alphabet Soup

This edition of the Maryland Pharmacist is jam packed—chock full—of information that is vital to the profession. Here we discuss HMO's and PPO's and DRG's and DUR's. All articles I am sure you will want to save for future reference. Also mentioned in this and other journals will be APhA, NARD, USP, DEA, MSHP, ASHP, FDA and on and on. We have become a society of "Alphabet Soup".

In the last month or so I have been in contact with several pharmacists who have other alphabetic concerns. Namely P.D.—what happened?? We held the great P.D. Debate in 1981 between Dean William J. Kinnard and Dr. David Clark; one of the best attended regional meetings conducted by the Association. And then on to the Convention held in Ocean City in June of 1981 where the overwhelming vote was pro P.D. and P.D. became the official designation of pharmacists in Maryland. At the Association office we have seen a change-over as more and more pharmacists have begun using the new designation. All levels of Federal, State and Local Government recognize and use the new designation when referring to pharmacists. While the Association does not recognize the old R.Ph. designation, I still see that many individuals have not switched over. Apparently this will be an evolutionary process.

Not to rehash the pro's and con's of P.D. vs. R.Ph., but surely any designation is better than R.Ph. (registered pharmacist) because we are *not* registered pharmacists.

Because of the original controversial nature of this subject, the Association has been fairly low-key in its approach. It has quietly encouraged the use of the new designation without staging a major public relations push. Having my roots we Baltimore, I have been a "Doctor" since shortly after my graduation even before my Board certification. I feel comfortable with P.D. and use it when communicating professionally. But I agree with folks who have called me. We need uniformity . . . we need the enthusiasm we had in 1981 . . . we need unity, something pharmacy seems to talk about all the time but still remains as one of our major concerns.

Sincerely,

Ronald Sanford

SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 3

Counseling Consumers on OTC Dandruff Remedies

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, OH

and

J. Richard Wuest, R.Ph., Pharm.D. Professor of Clinical Pharmacy University of Cincinnati Cincinnati, OH

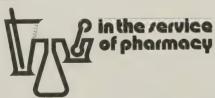
Goals

The goals of this lesson are to:

- review the etiology and treatment of dandruff and seborrhea;
- 2. discuss the pharmacology of drugs used to treat them.

Objectives

At the completion of the lesson, the successful participant will be able to:



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

- recognize effective OTC therapeutic agents for the treatment of dandruff and seborrhea;
- explain the proper technique for applying the discussed agents;
- 3. decide when the patient should be referred to a physician.

Most Americans have experienced at least one bout of dandruff and/or seborrhea sometime during their lifetime. Dandruff is the more common condition of the two, affecting an estimated 70 percent of the population. About 12 million Americans have experienced seborrhea. The potential magnitude of the market is further emphasized when one listens to or reads the advertisements of commercial products claimed to control these conditions. Dandruff and seborrhea can be safely and effectively self-medicated. But the precise cause of both conditions is not known. Therefore, some OTC remedies can offer little more than temporary relief of symptoms. In the minds of many consumers, however, relief of symptoms is satisfactory.

This month's article examines dandruff and seborrhea from a pharmacist's perspective. It reviews proposed etiologies for both conditions, and explains how pharmacists can distinguish between them. It also presents the proposed actions of OTC products which are intended to modify these conditions. Most importantly, it summarizes important information for consumers so they will receive maximal benefit from

these products.

Background

The skin is composed of two major layers, the dermis and epidermis. The dermis (inner layer) contains a rich supply of blood vessels that brings nutrients to all the skin layers. The epidermis ("epi" outer) is comprised of two major strata, neither of which has its own blood supply. The basal (lower) level of the epidermal

cells lies directly on top of the dermis and is, therefore, well supplied with its nutritional needs by fluids that diffuse upward from the dermis. The outer layer is not so supplied.

The cells that comprise the epider mis are continually formed in the basal level. They eventually migrate upward toward the skin's surface They die and become dehydrated as they approach the surface because there is insufficient nutrition to maintain their functions. These highly compacted, dead, and dr cells are known as the keratin (stra tum corneum) layer. As a result c the skin's normal "wear and tear, the outermost dead epithelial cell slough off and are replaced by net cells from underneath. The proces is continuous, usually requirin about 14 days from the time of for mation. The sloughing process i usually imperceptible since the cell are normally shed individually, rath er than in groups.

Dandruff and seborrhea share the same underlying bothersome symptom — an excessive epidermal shedding rate. Since the cells are lost in relatively large clumps (scales), but conditions are perceivable.

Dandruff

Dandruff is defined as a chroni non-inflammatory condition. It characterized by excessive sheddir of epidermal tissue lost in largelumps or scales that are dry, and a pear white or grayish. On the ski the condition is most common seen as small, round patches especially on the crown of the head. The sites occasionally itch. When excessive itching is present, a different dermatitis-related condition is much likely to be present.

Cause. The exact cause of dandris not known. Dandruff per se is radisease. It is a symptom of solother disorder. Poor hygiene do not cause dandruff, but it may wo en an existing condition. Most

© Merrell Dow

perts agree that dandruff occurs beause of a greatly increased rate of pidermal cell turnover. This rate is ntensified to the point that the new ells do not have time for complete eratinization, and, consequently, hey are shed en masse. Proposed, ut as yet unproven, theories relate andruff to improper diet, hormone mbalance, or to a deficiency of varius vitamins.

Many years ago observers discovred the presence of a yeast microoranism on the scalp of persons with andruff. This yeast was thought to e the cause of dandruff and a few eferences still state with authority nat this is indeed the case. This miroorganism has been identified as ityrosporum ovale, but has been iscounted as a cause of dandruff. P. vale can be found in similar conentrations on the scalps of persons ithout dandruff.

Other microorganisms have also een identified as potential causes of andruff. At present, however, none as been proven. It is interesting to ote that one organism, Propionibacrium acnes (a common cause of one), is found in lower concentraon on the scalps of individuals ith dandruff. Whether or not this icroorganism is linked to dandruff also not known at this time.

Symptoms and Occurrence. Scalig of large clumps of cells called juamae is the one universally visie symptoms of dandruff. Usually le flaking is seasonal, occurring ost frequently from October to Deember. Its occurrence and intensity ecrease through the spring months nd are least common during the ammer. This modulation probably flects seasonal humidity changes. hen the humidity is low, dandruff worse. As the humidity increases, andruff becomes less of a problem. andruff exhibits several other charteristics summarized in Table 1.

Dandruff is rare in youngsters uner age ten. It generally begins with aberty, peaking in the early twens. By middle and old age, its incince declines; it is rare in geriats. Men and women develop it to e same extent.

eborrhea

Seborrhea (seborrheic dermatitis). te dandruff, is characterized by

TABLE 1 Important Characteristics of Dandruff and Seborrhea

Characteristic	Dandruff	Seborrhea
Site	Scalp	See Table 2
Borders	Indistinct	Indistinct
Inflammation (redness)	No	Yes
Appearance of scales	Dry, grayish-white	Greasy
Age of onset	Puberty	Puberty
Itching	Variable	Usual
External factors that worsen		
condition	Cold weather	Stress, poor health
Rate of epidermal turnover	Twice the normal rate	More than twice the normal rate
Duration	Can persist for life, diminishing in middle and old age	Can persist for life, frequent exacerbation and remissions

an increased rate of epithelial cell turnover. The rate is greater than in dandruff. While dandruff is almost entirely localized to the scalp, seborrhea may occur on any hairy or skinfold area of the body. Its most common site, however, is the scalp (seborrheic capitus). Other locations are listed in Table 2. These areas contain the highest concentration of sebaceous glands.

TABLE 2 Usual Sites for Seborrhea

Armpits Back area between shoulder blades Behind the ears External ear canal Eyebrows and eyelashes Midchest Nasal folds Pubic area and groin Scalp

Causes. Numerous theories for the cause of seborrhea have been advanced over the years. None of them fully explain all aspects of the disorder, and whatever it is that initially triggers the process remains a mys-

According to the most frequently quoted theory, excessive sebum secretion provides a rich, oily, nutritional source for bacteria and yeast. These, then, convert this sebum to irritating substances (e.g., free fatty acids) that incite the local reaction and cause the symptoms. But while the term "seborrhea" describes excessive sebum flow, it still has not been shown that all persons with the condition have increased sebum production. In fact, carefully controlled studies have established that patients with the disorder frequently display sebum production characteristics that do not differ from their age-related counterparts who do not exhibit seborrhea.

The condition has also been linked to yeast and bacteria. For example, Candida albicans organisms are present in significantly higher numbers in infants with cradle cap. Pityrosporum ovale and Staphylococcus aureus are found in higher than normal concentrations in patients with seborrhea. However, the concentration of Propionibacterium acnes is more depressed in persons with seborrhea, than in persons with dandruff.

Like dandruff, seborrhea has also been linked to food allergies, vitamin B complex deficiency, immunological deficiency states, and to changes in the weather. The exact role that each of these factors contributes, if any, has not yet been determined.

Symptoms and Occurrence. The symptoms of seborrhea resemble those of dandruff in several ways (see Table 1). However, it is important to remember that the two conditions differ considerably. Seborrhea produces dull, yellowish-red lesions that are generally localized to one or a few areas of the scalp or other hairy surface. On occasion, larger areas may be affected. Common sites include the face, behind the ears, and upper trunk. These areas produce the most sebum and contain high levels of surface fats. Unlike with dandruff, itching is common in seb-

Whereas dandruff occurs at a relatively stable level, seborrhea bouts vary in time and in intensity. They can be severe one time, mild the next, then more severe than the first bout on the next occurrence. Many people report that during periods of stress seborrhea appears or flares up. It is also characterized by inflammation and crusting, and may involve the eyebrows and eyelashes and cause blepharitis (inflammation of

the eyelids).

Seborrhea is most commonly seen in middle-aged individuals and the elderly. Women are affected more frequently than men.

Seborrhea is also more common in patients with parkinsonism because these people have enhanced sebum secretion. When the tremors are controlled with medication, seborrhea improves markedly.

Cradle Cap. Cradle cap represents an infantile version of seborrhea. It normally involves the scalp, and the skin behind the ears, under the nose, and on the armpits, diaper area, and umbilicus. When it appears on the scalp, it usually occurs within the first couple weeks of life.

The condition results from accumulation of keratin and dirt on the baby's scalp and skin. Oftentimes the child's mother is hesitant to wash the scalp area well, fearing that permanent injury will result from applying pressure to the "soft spots" on the baby's head. This is, of course, an unfounded fear.

The condition normally clears within a month after birth and does not recur. On rare occasions it may evolve into a generalized itching dermatitis, and spread to the forehead, cheeks, and extremities. Except for those severe cases, cradle cap can be largely controlled by careful and thorough washing of the baby's scalp with water and ordinary soap. No special cleansing agent is necessary.

Treatment of Dandruff and Seborrhea

Treatment of both conditions is aimed at controlling the symptoms. Regular use of OTC remedies can be quite effective for this purpose. There are no known "cures." The action of most OTC products is based on the principle that if the large clumps of scales can be reduced in size, they will be less visible, and hence, the dandruff condition will be "controlled." Regular washing of the hair and scalp will help greatly. While this can be done daily, washing once every second or third day is frequently sufficient, except in severe cases.

Table 3 lists the therapeutic categories and representative OTC products that are marketed. These categories were reviewed by FDA's Advisory Panel on Miscellaneous

OTC External Drug Products. The panel's recommendations are listed in the table and are discussed below.

TABLE 3 Dandruff/Seborrhea Remedies Containing Ingredients Ruled to be Safe and Effective by the FDA Advisory Panel

Ā.	Coal Tar Derivative	s (Shampoos)
	Alma Tar	Pentrax
	Denorex	Polytar
	DHS Tar	Psorex
	Estar	Tegrin
	Iocon	Tersa-Tar
	Neutrogena T	Zetar
	Packer's Pine Tar	

В.	Salicylic Acid	
٠.	Domerine	Sebisol
	Ionil	Sebucare
	P and S	Xseb

C.	Selenium Sulfide	
	Selsun Blue	Sul-Blue

D.	Sulfur	
	pHisoDan	Sulfur-8
	Sulfoam	Sulpho-Lac

Zinc Pyrithione	Head and
Breck One	Shoulders
Danex	Zincon
	Breck One

F.	Salicylic Acid/Sulfu	r Combination
	Cuticura Anti-	Metab
	Dandruff	Sebaveen
	Diasporal	Sebex
	Fostex	Sebulex
	Glover's Medicated	Sebutone
	Klaron	Vanseb

Antiseptics (antimicrobials) have long been employed to treat scalp disorders. Their use is based on the theory that microorganisms are a possible cause of these problems. Antiseptics used include benzalkonium chloride, diiodohydroxyquin and povidone iodine. Their value in OTC dandruff remedies is questionable since, as discussed earlier, the microbial-induced theory for dandruff and/or seborrhea is not proven, and secondary infection is rarely encountered.

Cytostatics (e.g., selenium sulfide, zinc pyrithione) offer a more direct means for controlling dandruff. They reduce the rate of cell growth, and because there are fewer cells formed in any given period of time, scaling is reduced. These agents significantly reduce epithelial turnover of cells not only on the scalp, but anywhere on the body where the agents come

into contact with them. Seleniun sulfide has a direct depressant effect on cellular division; zinc pyrithion works nonspecifically as an epider mal cell toxicant. Some reports suggest that selenium sulfide acts mor quickly than zinc pyrithione to control the condition. This has not been substantiated clinically.

Keratolytics cause the keratin lay er to peel away, thus physicall removing the scales. They probabl act by dissolving the cement substance that bonds cells togethe. They do not dissolve keratin or provent scales from forming. As the scales are loosened, they can be

readily washed away.

Antipruritics are sometimes in cluded in dandruff and seborrhe products because the sensations pain and itching are transmitted t the same nerve fibers. Hydrocort sone has antipruritic, as well as ant inflammatory activity. Howeve dandruff is not an inflammatory co dition. The OTC advisory panel re ommended that temporary reli from itching does not effective control dandruff or seborrhe Therefore, its inclusion in OTC pro ucts intended for these uses will n be given final approval until add tional data are gathered and an lyzed.

Specific Suggestions of the FDA Advisory Panel

The list of ingredients in O'antidandruff and antiseborrh products reviewed by the FDA adsory panel is shown in Table 4. can be seen from the table, only fi agents were granted Category I (i safe and effective) status. These clude coal tar (formulated in sha poos only), salicylic acid, seleniu sulfide, sulfur, and zinc pyrithion

Coal Tar. This was shown to safe and effective when used shampoo form for treating dandr and seborrhea of the scalp. Consuers should be reminded that coal may stain clothing, skin, and he (especially gray, blond or bleache Coal tar imparts a strong odor a should be thoroughly washed off fore going out in public. Persousing a coal tar product should ave excessive exposure to the sun or traviolet light for at least 24 ho after applying the product, sin

TABLE 4
OTC Advisory Panel Categorization* of Dandruff/Seborrhea Ingredients

		ingi cuicitts
Ingredient	Category	Uses
Alkyl isoquinolinium bromide	Ш	D
Allantoin	III	D,S
Benzalkonium chloride	III	D
Benzethonium chloride	III	D,C
Borate preparation	II	D,S
Captan	III	D
Chloroxylenol	III	D,S
Coal tar preparations	I, III*	D,S
Colloidal oatmeal	II	D
Ethohexadiol	III	D
Eucalyptol	III	D
Hydrocortisone preparations	III	D,S
Juniper tar	III	D,S
Lauryl isoquinolinium bromide	III	D
Menthol	III	D,S
Methylbenzethonium chloride	III	C
Methyl salicylate	III	D
Phenol and Phenolate sodium	III	S
Pine tar preparations	III	D,S
Povidone-iodine	III	D,S
Salicylic acid	I	D,S
Selenium sulfide	I	D
Sodium salicylate	III	D,S
Sulfur	I	D
Thymol	III	D
Undecylenate preparations	III	D,S
Zinc pyrithione	I	D,S

^{*}Category I for shampoo use only; Category III for other uses

D = dandruff; S = seborrhea; C = cradle cap

hal tar may also cause photosensivity reactions.

Coal tar is suspected of causing ncer; chronic exposure to coal tar rivatives over several decades has en shown to be carcinogenic. The DA advisory panel concluded that al tar derivatives applied correctto the scalp (e.g., 5 to 20 mines maximum, 1 to 3 times weekly) ere safe for short term selfministration for dandruff. Howevsince a preparation applied to the dy to treat seborrhea may remain contact with the skin for longer riods, additional studies to clarify al tar's carcinogenic potential are eded. The panel recommended at coal tar products remain availa-OTC while these studies are derway. Paradoxically, FDA adviry panels that reviewed other pes of OTC products advised that al tar be removed from the OTC rrket.

balicylic Acid. The advisory panel peluded that salicylic acid, in lengths of 1.8 to 3 percent, was an active keratolytic to treat both adruff and seborrhea.

Sulfur. In a concentration of 2 to 5

percent, sulfur is considered to be safe and effective for topical use. It acts as a keratolytic, similarly to salicylic acid.

Selenium Sulfide. Used in shampoos in a 1 percent concentration, selenium sulfide was ruled to be effective for controlling dandruff. The 2.5 percent product is restricted to prescription use. The advisory panel had no data to support the use of selenium sulfide for treating seborrhea.

Used correctly, selenium sulfide is relatively nontoxic. While elemental selenium is quite toxic when ingested, there is little danger in absorbing toxic amounts when applied to intact skin. On broken skin (i.e., open lesions), the substance can be absorbed, and toxicity may occur.

Selenium sulfide has also been reported to discolor the hair. However, this does not appear to be a common occurrence. Individuals with dyed hair should test a small area with the shampoo to be certain no staining will occur. The shampoo should also be thoroughly rinsed off after use.

Zinc Pyrithione. Zinc pyrithione was concluded to be safe and effec-

tive for controlling dandruff and seborrhea. Concentrations recommended were 1 to 2 percent in shampoos, and 0.1 to 0.25 percent in other hairgroom products.

Consumer Advice

Specific consumer information has been discussed, but additional points on the use of dandruff or seborrhea products should be mentioned.

The hair and scalp should be washed with a regular shampoo prior to using the medicated product. This helps remove dirt and scales, and allows for enhanced penetration of the medicated product onto the scalp. Shampooing with a regular product may also be considered, following removal of the medicated product. This will help eliminate the objectionable odors and discoloring that some dandruff and seborrhea products impart to the hair and scalp. For mild dandruff, a non-medicated shampoo alone, used daily, should largely control the condition.

The medicated shampoo should be applied and left in place for the time specified on the label. A minimum period is 5 to 10 minutes. Massaging the scalp with a softbristle brush will assist in working the product down to the scalp.

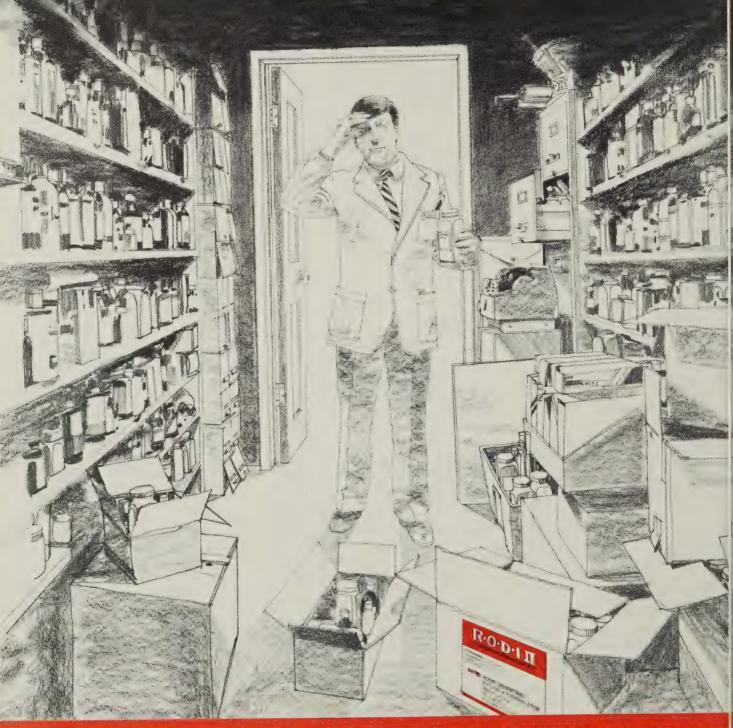
Pharmacists should advise consumers to avoid contact of any OTC product for dandruff or seborrhea with the eyes or mucous membranes. If it occurs, the area should be thoroughly rinsed with water.

Selenium sulfide may impart oiliness to the scalp and, in some cases, worsen seborrhea. Its use for this condition should be limited to once every second or third day. If the scalp is especially oily, a product containing salicylic acid and/or sulfur may offer greater benefit.

OTC dandruff and seborrhea products work quite well for most people. However, if a product fails to provide relief from the condition, another product with different ingredients and mechanism of action should be tried. If the condition does not improve after a couple weeks, the individual should consult a physician. A more serious disease state may be present.

Unless otherwise indicated (i.e., for products intended to treat cradle

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cap), OTC products for dandruff and seborrhea should not be used on children under age two. This precaution is warranted because their skin surface in proportion to body weight is greater than that in adults. Fur-

thermore, children do not have fully developed hepatic microsomal enzyme systems so they cannot handle potentially toxic substances that are absorbed.

To avoid possible damage to the

eye, seborrheic conditions that involve the eyelids should only be treated by a physician.

This and That About Pharmacy

by Leon Weiner, P.D.

Spotlight on SAM GOLDSTEIN, P.D.

Sam Goldstein, P.D., was born in Baltimore, MD, in March 1909. He attended City College, graduating in 1929. The following year, he matriculated at the University of Maryland, School of Pharmacy, where he graduated in 1930. In 1931, Sam married Sarah Feldman, sister of Milton H. Feldman, who also was a pharmacist graduate of the University of Maryland. That same year, Sam purchased Lincoln Pharmacy on Calhoun Street in Baltimore City where he remained proprietor until 1968.

Good sense, parental guidance, and direction resulted in their two lovely daughters, Ettadean and Simone, meeting and marrying graduates of the University of Maryland, School of Pharmacy, Irwin Epstein, Class of 1956, and Larry Rosenbloom, Class of 1957. Ettadean and Irwin's son, Larry, is also a graduate of the University of Maryland, but from the School of Dentistry. Their younger son, Mark, a graduate of Towson State University, is an accountant and computer analyst who is presently employed by the Chase Manhattan Bank of New York. Sam's daughter, Simone and her husband Larry, have a daughter, Jamie, who is graduating this year from the University of Maryland, School of Medicine Medical Technology program. Their son, Michael, is attending York College of Pennsylvania, as a computer science major and their youngest daughter, Laurie, is attending high school.

As for Sam's sons-in-law, Irwin Epstein is, at the present time, out of the pharmacy profession but in the past he has worked for Read Drug and Chemical Company and for Giant Drug Company. Larry Rosenbloom is the owner of Stoney Creek Pharmacy on Fort Smallwood Road and in the past was one of the partner-owners who ran the Action Drug Chains in the Baltimore area.

Dr. Sam has been very active in the pharmacy profession for many years. He had held the offices of presidency for the Maryland Pharmaceutical Associa-



Because Sam and Sarah are so much respected and loved by all who know them, we decided to give you a double treat. Above are the Goldstein's in duplication, thanks to the magic of the mirror

tion, the Baltimore Metropolitan Pharmaceutical Association, the University of Maryland Pharmacy Alumni Association, the Alumni Council of Greater Baltimore, the "Rx Club", the Baltimore Veteran Druggist Organization, and the Alumni International.

As the saying goes, "Behind every successful man, there is a good woman". Sarah exemplifies this for Sarah and Sam are indeed a devoted team. Sam, assisted by his charming wife, Sarah, has been chairman of many social events for both the Pharmacy School as well as the Pharmacy Associations. To mention a few, there was the Alumni Frolic which was an affair for the students and faculty of the Pharmacy School, the B.M.P.A. banquets, and the Alumni Association banquets. In addition, Sam has served on countless committees and was always available whenever an individual or committee needed help. He could always be counted on to provide it.

Dr. Sam's family and friends are particularly proud of the many honors bestowed upon him. In 1974–75, he was named Honorary President of the Alumni Association; in 1979, he received the Honored Alumnus Award of the School of Pharmacy; and in 1981, he received the "Bowl of Hygeia" Award. This award provides special recognition to the men and women of pharmacy for their many and varied community services. Sam won special recognition for his involvement

in the Elder Ed program which educates senior citizens in health care with regard to drug related issues.

Because of Sam's warm personality and sense of humor, he has won the title of the unofficial resident chaplin and toastmaster of the pharmacy associations. May Sam continue to be a vital and zealous member of the profession he has given so generously to and with such endless devotion.

PHARMACY CHANGES—February 1985

The following are new pharmacies in the State of Maryland:

Aspen Heights Pharmacy 2926 Baltimore Blvd. Finksburg, MD 21048

The Pharmacy at O'Donnell Square 2920 O'Donnell St.
Baltimore, MD 21224

Care Plus, Inc. 9130C Red Branch Rd. Columbia, MD 21045

The following pharmacies have change of address:

Sav-More Pharmacy 7120 North Point Rd. Baltimore, MD 21219

Twin Knolls Pharmacy One Knoll North Dr. Columbia, MD 21045



Above, to the left, is a picture of Noble Phillip Redmond, P.D., as he appeared in his University of Maryland Pharmacy Yearbook of 1958. To the right, 26 years later, Phil and his beautiful wife Suzanne appear at the public inauguration of the Institute for the Prevention and Control of Violence and Extremism which took

Get Well Wishes to:

Bernard F. Macek, P.D., UofMD Pharmacy 1956, who recently underwent surgery at Johns Hopkins Hospital. Bernie, former owner of Patterson Park Pharmacy, is now working at the Highland Health Facility Pharmacy, 5200 Eastern Ave., Baltimore, MD. As everyone who worked for Read's Drug and Chemical well remembers, Bernie is the lucky guy who married Treasure. She was the attractive, cheerful young lady who worked the telephone switch boards for the company.

Recent Pharmacy Deaths:

Sister Lelia Sheedy, DC—age 98. Died February 23, 1985 at Emmitsburg, MD. Trained as a pharmacist while serving at St. Vincent's Hospital in Philadelphia, PA, from 1909 to 1929. Was a pharmacist at Sisters Hospital in Waterville, MA and also at a Norfolk Hospital.

Jacob (Jack) Serpick, P.D.—age 81. Died February 13, 1985. Graduated UofMD Pharmacy 1925. Former owner of St. Paul Pharmacy in Baltimore City. Is the father of David Y. Serpick, P.D., UofMD Pharmacy 1962.

Thomas Henderson Kerr, P.D.—age 96. Died March 5, 1985. Graduated Howard University School of Pharmacy in 1912. Owned and operated the 723 George Street Pharmacy for 40 years from 1919 to 1960.

In case you missed it, guess who was advertising for pharmacists in the Sunday Sun, March 10, 1985 edition? It was Murphy Mart Pharmacy and Valu Pharmacy (Division of Valu Food).



place at the Joseph Meyerhoff Symphony Hall in Baltimore City. Dr. Redmond is a long time employee of Noxell Laboratories in Baltimore County. At one time, he also was a partner in the Redmond MacLarty Pharmacy on Falls Road, Baltimore.



Above, to the left, is a picture of Shellie C. Cassel, P.D., as she appeared in her University of Maryland Pharmacy Yearbook of 1977. To the right, seven years later, Shellie is seen as she is being promoted to Director of Pharmacy Services at North Charles Gen-



eral Hospital in Baltimore. Dr. Cassel has been at this hospital since her graduation. In addition, she also serves as editor of the hospital's pharmacy newsletter.

Quick Reminder—The CDS Inventory is to be taken this year on May 1, 1985. For more details, read the Division of Drug Control mail-out letter dated March 1, 1985, page 6 and USP 21, page 1296–1297, pharmacy journals, etc. If you still have questions, the telephone number for DEA in Washington, DC is 202-724-6061.

Charles H. Tregoe, Chief, Division of Drug Control, announces that the Division will be moving to its new location of Howard and Lexington Streets sometime this coming June. The Division of Drug Control will be housed on the eighth floor of the Hecht Company building in downtown Baltimore City. As more information is available, we will make it known.

Health Maintenance Organization Survey

by Kathy Parker MPhA Student Intern

The concept of Health Maintenance Organizations (HMOs) is not a new one. The first medical cooperative originated in Oklahoma in 1927 and was the forerunner to the medical care foundation (MCF) of prepaid group practice later organized in California.

The American Medical Association (AMA) was quick to label prepaid group practice as "corporate medicine" and as a result HMOs were opposed by traditional practice and experienced a slow growth rate until recently.

On December 29, 1973, during the Nixon Administration, the HMO Act of 1973 was enacted. This was an attempt by the federal government to slow the growth of health care expenditures. The objective of the Act was to stimulate the growth of more HMOs in the U.S. as an alternative to traditional medical care in an attempt to contain increasing health care costs. The government felt this could be attained by providing an organized system of health care, to a voluntarily en-

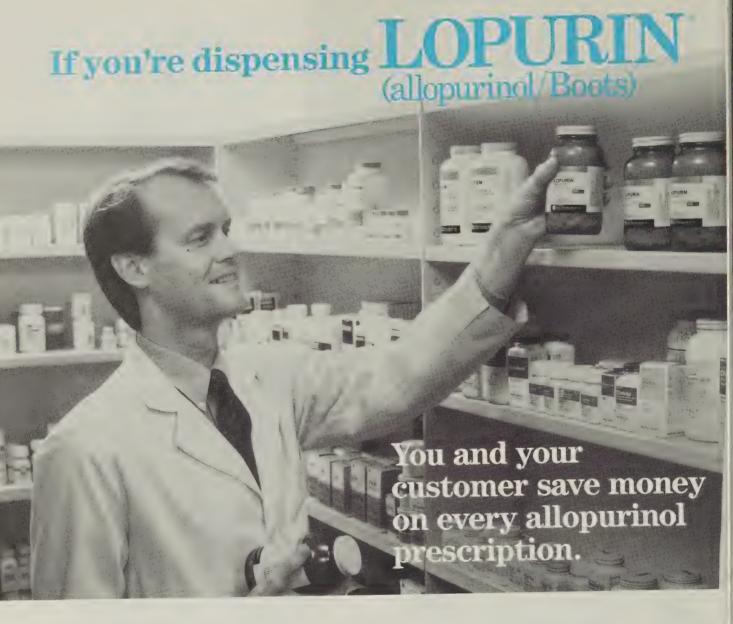
rolled population, at a prepaid fixed premium, for a defined set of benefits.

The Law provided grants, loans, and loan guarantees to existing "qualified" (according to DHEW standards) plans and to the development of new HMOs. The Law also removed the legal barriers of the states that prohibited physicians from working in corporations.

In addition, the Law provided a "dual choice option" which cracked the employer barrier and mandated that (with 25 or more employees) if a health care plan was used than the employer had to offer a choice to the employees between a HMO and another health care plan (such as BC/BS or commercial insurance policy).

In 1972 there were approximately 20 HMOs in existence in the U.S. and by 1980 the number of HMOs had grown to 240. Today there are approximately 350 HMOs in operation in the U.S.

Physicians in private practice are realizing the con-



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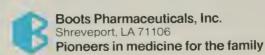
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sequence of prepaid health care plans and are finding it necessary to market the benefits of their independent primary care practices to their patients. They are faced with a shrinking patient population due to the competition from neighboring HMOs. In an attempt to recapture a portion of their declining income, some physicians are turning to the dispensing of prescriptions as a part of their office visits.

Independent pharmacy as well, is faced with the same declining patient population as a result of competition from HMOs. The dilemma to pharmacists has a different perspective than that to physicians. Physicians have to enlist the allegiance of their remaining patients to remain with their private practices. Pharmacy, however, is being squeezed out at the other end of the HMO benefits package. Patients are limited in their freedom of choice of pharmacies where they can have their prescriptions filled.

In an attempt to find out just how limited the pharmacy benefit of HMOs is here in the Baltimore/Wash-

ington metropolitan area, MPhA conducted a survey in February of this year. Fourteen Maryland licensed HMOs were sent the following questionnaire:

Does your HMO Plan offer pharmacy services? YES _____ NO ____

If YES, do you have an on-premises pharmacy? YES _____ NO ____

If YES, may your subscribers use other pharmacies? YES _____ NO ____

If no on-premises pharmacy, are pharmacy services obtainable only at selected pharmacies, or may subscriber go to the pharmacy of his/her choice?

Selected pharmacy ____ Pharmacy of Choice ____

If selected pharmacies only are available, would your HMO consider accepting a contract with independent pharmacies, if handled through a processing service?

YES ____ NO ____

Table 1

		Pharmacy			Subscribers may use other pharmacies		No on-premise	No on-premise	Must use selected pharmacy, but would
	Pharmacy services offered	services not offered	On-premise pharmacy	No on-premise pharmacy	Yes	No	pharmacy— must use selected pharmacy	pharmacy— may use pharmacy of choice	consider contract with independent
Chesapeake Health Plan Baltimore, MD	X			X	Х			X	
Choice Health Care Plan Baltimore, MD	X			X	Χ		X		Х
Columbia Medical Plan Columbia, MD	X		X			Χ			
Constant Care Medical Center Baltimore, MD	Х		Х		X Limited				X
Delmarva Easton, MD	Х			X				X	Χ
Free State Towson, MD	Х		X in some Med. Ctr.	Х			X (Giant)		X
George Washington University Plan Washington, D.C.	X		X		X Limited				X
Group Health Association Washington, D.C.	X		X		X Limited				
Health Care Corp. of Mid-Atlantic (Care First) Baltimore, MD	Х			Х			X (Giant & Rite Aid)		X
Health Plus Riverdale, MD	X			Х				X	
Johns Hopkins Health Plan Baltimore, MD	X		X		X Limited				Х
Kaiser Permanente Health Care Program Washington, D.C.	X with Rider		X some sites	Х	Х		X		×
MD-Individual Practice Assoc., Inc. Rockville, MD	X			X			X		Х
West Baltimore Community Health Care Corp. Baltimore, MD	X		X			X			

Results were received from all 14 HMOs and are shown in Table 1.

In summarizing the results of the survey, all 14 HMOs offer pharmacy services. Kaiser Permanente Health Care Program requires an extra rider to be attached to the policy for pharmacy services to be included in the coverage. Eight of the organizations offer on-premise pharmacy services. Free State and Kaiser Permanente Health Care have on-premise pharmacy services only at limited sites. At the medical centers in which Free State does not have on-premise pharmacy services available, their patients must use Giant drug store for their pharmacy services. Likewise, the Kaiser group limits their patients to pharmacies they have contracted with at sites where on-premise pharmacies are not available. Columbia Medical Plan mentioned that in some satellite areas, pharmacy service is contracted with local pharmacies, and that exceptions are made at times when the on-premise pharmacies are not open or if the patient is out of the area coverage. They also noted that they would prefer to use a local independent pharmacy over a chain store, but each site is decided individually. Constant Care Medical Center also allows a limited number of off-premise pharmacies to be used, such as Rite Aid and MacGillvray. George Washington University Plan has a co-pay agreement with People's Drug in their limited use of off-premise pharmacies. Group Health Association (GHA) allows some of their patients to use the prepaid drug plan administered through the PCS participating pharmacies. Johns Hopkins also allows a limited number of off-premise pharmacies to be used, but did not state how many or which pharmacies. West Baltimore Community Health Care Corporation has on-premise pharmacy services and does not allow their subscribers to use other pharmacies.

Of the six remaining groups that do not offer onpremise pharmacy services, three limit their patients to selected pharmacies and three give their patients freedom of choice for pharmacy services.

Out of the 14 HMOs surveyed only one (West Baltimore Community Health Care) definitely said "no" to contracting with independent pharmacies if handled through a processing service. The others are already handling some of their pharmacy services through independents or are willing to consider independant pharmacy service contracts that meet their particular HMO criteria.

In concluding, independent pharmacists must realize the potential loss of patients as HMOs proliferate. If HMOs stipulate which pharmacy the patient must use in a particular HMO plan then the patient's freedom of choice to use his preferred pharmacist is curtailed. However, when a patient joins a HMO he must abide by the defined set of benefits which may include the use of a specific pharmacy.



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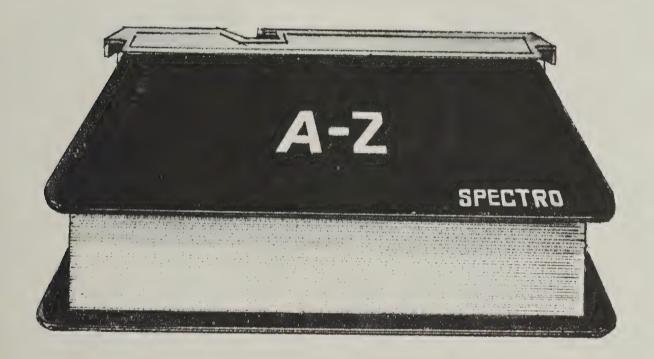
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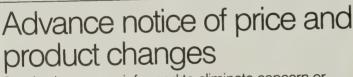
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Don't Let Them Tell You Where To Go!

There are many new health insurance programs available today. Many of these involve innovative features designed to improve the health care you receive. But many also contain a rather unwelcome feature. Unlike traditional health insurance, these new plans, such as Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs) often take away your freedom of choice in selecting the health professionals, hospitals, and pharmacies where you are permitted to obtain care. Sometimes you are given the option of going to the physician or pharmacy of your choice, but only at an increased out-of-pocket cost to you. Many patients discover too late that their new health coverage doesn't permit them to continue having their prescriptions filled at the pharmacy of their choice. Often they must go to a pharmacy that is less conveniently located, or that may have less convenient hours, or may not offer the range of services that is desired.

It is important that you consider these factors when you make your decisions regarding the type of health coverage you will obtain:

- Know the specifics of the plans you are considering
- Understand what options you may or may not have regarding the selection of the pharmacy (or doctor or hospital).
- Consider the importance of service, convenience, and confidence in the selection of a pharmacy.

There's Another R. That's Not For You

It's only human nature. You like to save a few dollars when you shop, don't you? After all, who doesn't like a bargain? But when you buy prescription drugs by mail do you really want to bargain away your health?

Mail order drug programs are another instance of someone telling <u>you</u> where to go! Mail order prescription drugs <u>may</u> mean cheap drugs, but when you buy by mail here's what you're missing:

- Personalized service from the "drug expert" your pharmacist — who knows which other drugs you may be taking that would interact dangerously with your new prescription and whether you might be allergic to the new medication.
- Your own "consultant," right there in the pharmacy to answer your questions about this medication and other non-prescription items you may want to use.
- Access to your pharmacist, in an emergency or on a 24-hour basis or even at home when you can't get to the pharmacy because of illness.

The next time your health plan describes the "benefits" of mail order prescription drugs, ask yourself these questions:

- What do you do until the medicine arrives in the mail?
- What do you do if the medicine is lost?
- What do you do if the medicine is stolen?
- Is your medicine safe from temperature extremes and other dangers while on its way to you?
- What do you do when the medicine you take runs out? How long will it be before you can be resupplied?
- Do you really want to receive larger than normal quantities of a medicine, which can lead to abuse and waste?
- Do you really deserve fourth-class health care?

Let's face it: Your pharmacist knows you — the nature of your health problem and why you're taking certain drugs to help solve that problem. He or she knows this because a patient profile is kept on persons like you who desire quality pharmacy services. Your pharmacist also knows you, because he or she is right there in your hometown, an important part of the business and professional community serving you and your family. The mail order prescription drug business doesn't know you or your special needs, the way your pharmacist does.

Do you really want to give all this up — the quality of your health care — to save a few dollars?

Think about it for a minute.

We believe you'll agree: Mail order prescription drugs are **no** bargain.

This message is from your community pharmacist and the Maryland Pharmacists Association . . . We're concerned.

COST CONTAINMENT MEASURES FOR PHARMACEUTICAL SERVICES IN MARYLAND

Arthur Schwartz Steven Miller

The health care system in the United States is undergoing a drastic change in philosophy. The health care system was based on the premise that the highest levels of care should be *sin qua non*. This has led over the past few decades to the introduction of half-way technologies, expansion of the number of hospital beds, and tremendous outlays for medical and pharmaceutical research and services. The benefits derived from such advances in the health care system have come at an extremely high cost, especially when considering the marginal increase in the quality of care realized from such advances.

This concern has led to the reversal in the philosophy that the highest levels of quality of care are to be had at any price. The health care system has come to the realization that the cost of care is becoming a real burden on the system. Cost containment is becoming the guiding force as the 21st century approaches. Further, the cost containment philosophy is not restricted to any one sector of the health care system. Hospital, physician, and pharmaceutical services are all feeling the effects of the cost containment measures being imposed. Neither are there any geographic restrictions.

This paper focuses on cost containment for pharmaceutical services in the state of Maryland. Since the paper is focused in this manner, generalizations beyond the context of this paper must be made with the realization that political and regulatory environments do differ from state to state and from service to service. Since cost containment is a nationwide concern, however, the ideas expressed here have some merit as possible policy measures throughout the country.

Up to this point, the idea of cost containment has been mentioned several times. It then seems requisite at this point to define the terms "cost containment." Cost containment goes beyond the narrow idea that savings in the pharmaceutical services sector, without re-

gard for the impact on the other sectors of the health care system, is truly cost containment. Cost containment must be defined by the impact a measure has on the total health care system. Therefore, measures that lead to shifts of costs in the health care system from one sector to another do not necessarily lead to cost containment.

Research has shown that shifts out of the pharmaceutical services sector may indeed lead to more expensive alternatives. For example, implementation of a co-payment for the purchase of a prescription, if it inhibits the patient from obtaining the medicine, resulting in the patient ultimately suffering more severe consequences that lead to hospitalization, is a cost shift. Studies of the MediCal program by Bryan and Gibbons demonstrated an increase in morbidity for certain patients with the implementation of a co-payment. This suggests that although the pharmaceutical services sector realized some "cost containment," the health care system *in toto* has realized just the opposite.

For the purposes of this paper, cost containment has been defined to reflect the authors' philosophy about the proper role of cost containment in the health care system. We then offer the definition of cost containment as, "those measures that lead to a reduction in costs for one sector of the health care system that do not adversely impact on costs in another sector of the health care system." With this definition as a guide, five cost containment measures that the authors believe have merit as possible measures to impact on the pharmaceutical services sector of the health care system presently in place in the state of Maryland are presented. Although there are numerous measures that fit into the definition of cost containment, the list presented reflects what the authors feel are the more effective and efficient measures. The five cost containment measures chosen and discussed are:

- 1. Bids and the bidding process
- 2. Therapeutic alternatives
- 3. Formularies
- 4. Drug utilization review
- 5. Costing mechanisms (AWP, AAC, etc.)

Arthur Schwartz, BS Pharm, MS, MBA, R.Ph.; is a Ph.D. candidate and Steven Miller, BS Pharm, R.Ph.; is an M.S. candidate: both from the Department of Pharmacy Practice and Administrative Science, School of Pharmacy, University of Maryland at Baltimore.

These five measures were chosen based on two criteria. First, an extensive review of the literature was done. This led to the conclusion that these are measures that will shape pharmaceutical services cost containment in the future as it will be applied to the state of Maryland. Second, since the impact will be felt by pharmacy practitioners from all areas of practice, these measures appear to have a degree of commonality between the measures themselves and the different practice settings of the pharmacist. Clearly then, the measures presented, although based on some degree of empirical evidence, are a matter of conjecture. It is with this caveat that we now proceed to discuss each of the cost containment measures.

Bids and the bidding process

Bid purchasing is the process by which drugs are secured at the lowest possible price, and as such, prices are fixed for some predetermined length of time.2 Bids have their greatest impact on drugs that are multisource, that have been on the market for some time, and that would demonstrate a fair degree of cost savings with volume purchase. The past has shown that hospitals have been the primary users of the bid process. With the rapid growth in the numer and size of Health Maintenance Organizations (HMO's), and with the increasing number of outpatient prescriptions dispensed by hospitals, the bid process is finding its way to the community setting. Further, as more and more third parties become the payers of pharmaceutical services, bid agreements would lend themselves nicely to the community setting.

Although tried with little sucess so far, it is the authors' opinion that such a mechanism can and will be commonplace in all pharmacy practice settings. As a cost containment measure, the bid process would have a tremendous impact. From the pharmacist's point of view, such a measure locks the pharmacist into a narrow range of drugs from which to choose. Since the bid process is between the payer (the third party) and the supplier, the practitioner is in effect stuck in the middle. Contracts made between the two parties lead to procedures carried out, but not influenced by, the pharmacy practitioner. Hence, one of the main professional responsibilities of the practitioner, to choose the brand of medicine based on the professional's opinion of the alternatives, is circumvented. This is, however, the reality of the bid process.

Therapeutic alternatives

Therapeutic alternatives have been defined as "those drugs that are chemically related, but not identical drugs." For the purpose of this paper therapeutic alternatives will include both chemically related, but not identical drugs (e.g., drugs that differ in their salts, dosage form, etc.) and drugs in the same therapeutic class (e.g., cardioselective beta blockers). From a historical perspective, the concept of therapeutic alterna-

tives has developed from the efforts of pharmacy and therapeutics (P&T) committees to limit the number of drugs used in the committee's institution. The initial thrust was to select a specific brand of a drug and to have only that brand on the formulary. This results in a narrow selection from which to choose, but at the same time reduces the inventory costs associated with a larger formulary. Clearly, such a cost containment measure has its start in the hospital setting. With the increase in HMO pharmaceutical services, however, the authors believe the use of therapeutic alternatives has been moving toward the outpatient environment.

The authors feel, however, that this is as far as this cost containment measure may go. The reason for this conclusion is based on the premise that physician-pharmacist interaction must be maintained at a high level to successfully apply this cost containment measure. In the hospital and HMO settings this close degree of interaction is possible. In the community setting, however, this degree of interaction seems quite unlikely.

It must be added that, as with bids, as the payers for pharmaceutical services become increasingly limited to a small number of third parties, the mechanisms for implementing therapeutic alternatives (such as contractual agreements) may make the use of therapeutic alternatives prevalent throughout all areas of pharmacy practice. Although the implementation of therapeutic alternatives may be a cumbersome and involved process for the community practice setting, the cost savings realized could make this mechanism a reality. For example, cost savings between certain expensive forms of tetracyclines and cephalosporins and their less expensive therapeutic alternatives translate into significant cost savings to the payer if therapeutic alternatives are used.

Formularies

A formulary represents the official compilation of drug products that have been sanctioned for use in a given environment. This definition serves as a basis for defining formularies, but some clarification is needed. A formulary is not merely a drug list, although some drug lists are wrongly called formularies. A formulary is not only a list of drugs, but also includes indications for the use of each drug, how the drug is to be administered, and other ancillary information needed to make an intelligent and informed decision. Based upon this definition, a formulary has merit as a cost containment measure.

Formularies are certainly not a new idea. The first formulary dates back to 1811.⁵ It was not until after the turn of the 20th century that formularies moved away from the "drug list" character to the comprehensive idea of a formulary as it is known today. Even still, in 1976, only about 65% of all teaching hospitals had a formulary.⁶

Restricting prescribing orders to formulary choices will generate savings not only by limiting the drugs

available, but also by providing information on the optimal therapeutic regimen available.

It is apparent that formularies have been misunderstood and poorly utilized in the past. One only has to examine "formularies" proposed by third party payers, especially the Maryland Medicaid program, to see that these are merely drug lists, and not formularies in the true sense. It is not surprising then that some of the current research in the area of formularies has indicated that limited cost savings are realized by the implementation of a formulary. One could even take the position that the use of a closed formulary leads to increases in the cost of the health care system. If formularies, in their expanded role, however, were implemented in all settings of pharmacy practice, the cost containment realized would be substantial.

Drug utilization review

Drug utilization review "involves the application of medical and economic criteria to drug selection and use by the physician and in turn by their patients." Application of DUR to examine different courses of therapy and to study the use of different drugs has become widespread in recent years, attesting to DUR's success as a mechanism to objectively validate the use of various drugs. With the shift in philosophy to the cost containment aspects of health care, the role of DUR has also shifted.

The definition offered states that DUR involves medical and economic criteria. The "quality first" of the past coincided well with the application of DUR to medical criteria. The emphasis is shifting now to applying DUR to the economic criteria as well. This is clearly a result of the philosophical change in the health care system mentioned previously. DUR is a viable method for use by health care program administrators and insurance companies to hold down unjustified increases in the cost of a drug program.

It then is natural for DUR to leave its hospital environment and venture out into the community practice setting. Again, as prescription services are increasingly being paid for by third parties, the economic incentives for making DUR a part of any coverage seem to be justified. It is on this premise that DUR, as a cost containment mechanism, will make its role into all sectors of pharmacy practice.

Costing mechanisms

Since reimbursement for pharmaceutical services is usually a professional fee and the cost of the medicine, attempts to get at the true cost of a drug have been made for many years. With the advent of third parties in the mid 1960's (especially Medicaid) the issue of reimbursement has been examined. In the past, the Average Wholesale Price (AWP) has been the standard for reimbursement. The AWP, however, has been shown not to be the true cost incurred by the pharmacist.

Thus the Actual Acquisition Cost (AAC) has come into play as the real basis on which to reimburse the pharmacist. The difference between the two (AWP versus AAC) has been measured to be between 10% and 18% on the average. 10

Such a large degree of difference has caused administrators to look at AAC as a true cost containment mechanism. But this issue goes one step further. Along with the cost difference, the implementation of costing mechanisms in general is operationally simple. That is, contractual agreements between the third party payers and the providers of pharmaceutical services are easily worked out before implementation of the contract. So the real savings, and the ease of implementation make the issue of appropriate and fair costing mechanisms one that will certainly be relevant in the near future. The authors see the movement away from AWP toward AAC (or a similar alternative) as manifest. The greatest impact of changes in this costing mechanism is clearly on the community practitioner. It is this group of pharmacists who will be the most heavily influenced by this move, and on whom the impact will be a real burden.

The five mechanisms presented are all distinctive ways in which cost containment will be realized in the practice of pharmacy. There is, however, as mentioned before, a degree of commonality between the mechanisms. We feel strongly that the initiation of any one mechanism, without impact on the others, is a very unlikely occurrence. We then predict that as cost containment mechanisms come into play for pharmaceutical services, the mechanisms will come as a set. The impact will be more than simply the sum consequences of each of the mechanisms. The impact will be a synergistic melding of the mechanisms.

The result may be a drastic change in the way pharmaceutical services are reimbursed. As stated throughout, the authors are aware that these changes will be implemented by third party payers of pharmaceutical services. As practitioners, it would be prudent to anticipate these mechanisms coming into place and take appropriate action to minimize their impact on the way pharmacy is practiced in the state. It is incumbent upon the practitioners of pharmacy, as a profession, to analyze these changes in the environment of pharmacy practice. The profession should draft appropriate responses as to the future impact that these mechanisms will have on the way we, as practitioners, will practice our chosen profession.

ENDNOTES

¹ Brian EW, Gibons SF. California's Medi-Cal copayment experiment. *Med Care* 1974:12(12) suppl.:1–303.

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⁵ ibid, 32.

6 ibid, 32.

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8 Smith MC, Knapp DA. Pharmacy, Drugs, and Medical Care. 2nd ed. Baltimore, MD: The Williams and Wilkins Company. 1976;228.

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Office of the Inspector General, 1983.

The Supreme Court of the United States

(The following brief summary of the Portland Retail Drug Supreme Court Decision is provided to members for their information and future reference. The MPhA is frequently asked for copies of this Decision for use by both hospital and community pharmacists.)

Syllabus

ABBOTT LABORATORIES ET AL. v. PORTLAND RETAIL DRUGGISTS ASSN., INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 74-1274. Argued December 16, 1975—Decided March 24, 1976

Respondent, as assignee of more than 60 commercial pharmacies, brought this antitrust action against petitioners, 12 drug manufacturers, charging that by selling drugs to certain hospitals, each of which has a pharmacy, at prices lower than those charged to respondent's assignors, petitioners violated the Robinson-Patman Act, which makes it unlawful for one engaged in commerce to discriminate in price between different purchasers of like commodities where "the effect . . . may be substantially to lessen competition." 15 U.S.C. § 13(a). Petitioners claimed that the challenged sales were exempt under the Nonprofit Institutions Act, which, inter alia, excludes from the application of the Robinson-Patman Act nonprofit hospitals' "purchases of their supplies for their own use." §13c. The The District Court ruled on the basis of the evidence adduced that the hospitals involved were nonprofit and that their drug purchases were "for their own use" within the meaning of §13c, and granted summary judgment in favor of petitioners. The Court of Appeals vacated and remanded. While agreeing that the designated hospitals were nonprofit, that court concluded that a hospital's drugs are purchased for its "own use"

only where the hospital can be said to be the consumer, *i.e.*, where dispensations are to inpatients and emergency facility patients. *Held*:

- 1. Section 13c does not exempt all of a nonprofit hospital's drug purchases from the Robinson-Patman Act but the exempting language must be construed as applying to what reasonably may be regarded as use by the hospital in the sense that such use is part of and promotes the hospital's intended institutional operation in the care of its patients. Pp. 6–12.
- 2. Applying the foregoing rule, drug purchases by a nonprofit hospital are exempt as being for the hospital's "own use" if the drugs are dispensed:
- (a) To the inpatient for use in his treatment at the hospital; the patient admitted to the hospital's emergency facility for use in his treatment there; or the outpatient for personal use on the hospital premises. Such dispensations are part of the hospital's basic function. P. 12.
- (b) To the inpatient, or to the emergency facility patient, upon his discharge, and to the outpatient, all for off-premises personal use, provided these takehome dispensations are for a limited and reasonable time, as a continuation of, or supplement to, hospital treatment. Pp. 12–13.
- (c) To the hospital employee or student for personal use, or for the use of his dependent. Each is a member of the hospital family and dispensation to him furthers the hospital's functions. Pp. 13–14.
- (d) To the physician staff member for his personal use or the use of his dependent. Here the considerations are similar to those in (c), *supra*. Pp. 14–15.
- 3. Purchases for the following types of dispensation are not exempt since they are not for the hospital's "own use":
- (a) To the former patient, by way of a renewal of a prescription given when he was an inpatient, an emergency facility patient, or an outpatient. The purpose of the exemption has been exceeded where the connection with the hospital has reached the refill stage. P. 13.
- (b) To nondependents of those covered in $\P2(c)$ and (d), *supra*. These relationships are too attenuated for the statutory benefit. Pp. 14, 15.
- (c) To the walk-in customer, who has no present connection with the hospital or its pharmacy (except in the occasional emergency situation, which can be viewed as *de minimis*). Pp. 15, 16.
- 4. Under these standards the hospital can either put all the drugs it purchases to its "own use" exclusively, or can keep separate records for the drugs put to its "own use" and for those otherwise dispensed, making accounting submissions to the supplier for price adjustments. The supplier is protected from antitrust liability if he reasonably and noncollusively relies upon the hospital's certification as to its dispensation of drugs purchased from the supplier. Pp. 17–18.

510 F.2d 486, vacated and remanded.

56 31/1 =

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Robert Snyder, Commissioner of the Maryland Board of Pharmacy, was a featured speaker on Home Health Care at the U.S. Pharmacopeial Convention held March 22–24, 1985 in Washington, D.C. Bob will soon be leaving the Board after representing hospital Pharmacy there for ten years.



Nathaniel Futeral, President of the Baltimore Metropolitan Pharmaceutical Association (left), presents Martin Mintz (right) with the BMPA Past President's Award. The presentation was made at the annual BMPA Banquet held on March 10, 1985.



Marion Nastalski and Walter Zajac (left to right), owners of Rosedale Medical Center Pharmacy, receive an award from Abbott representative Bill Kilburn in recognition of filling their one millionth prescription.



Jack Peters (right) was named BMPA Honorary President for his long association with Pharmacy through his position as a representative with Squibb and he received the Honorary President Award from President Futeral. The Banquet was again held at the Blue Crest North in Baltimore.

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Eli Lilly and Company Indianapolis, Indiana 46285 ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN REFINEMENT, PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE*, ETC.), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.



MPhA Convention



Ocean City, Maryland



Program At A Glance



Sunday June 23

Registration Open at 12:00 Noon (rooms available at 3:00 p.m.) Wine and Cheese at registration desk sponsored by Berkey Photo Tennis, Golf, Swimming, Special gifts and "Goodie Bags". Programs and tickets available.

9:00 p.m. Welcoming Cocktail Party Sponsored by the Drug House.



Monday June 24

8:00 a.m. Exhibits Open. Coffee and donuts.

9:00 a.m. Joint Session with Delaware. Sponsored by Parke Davis—"Consulting in the Community Pharmacy."

10:00 a.m. LAMPA Brunch and Fashion Show.

Delaware C.E. Program in the afternoon

6:30 p.m. Crabfeast and Chicken at Berlin Fire Hall—Square Dance—Joint with Delaware.



Tuesday June 25 8:00 a.m. Exhibits Open. Coffee and Donuts.

9:00 a.m. Opening General Session House of Delegates.

Delaware C.E. Program in the afternoon

8:00 p.m. Cocktail Party sponsored by Loewy Drug Co.

Delaware Banquet in the evening



Wednesday June 26 9:00 a.m. Second Business Session of the House of Delegates. Resolutions, Installation of Officers, Committee Reports.

6:00 p.m. Cocktail Party sponsored by Youngs Drug Products.

7:00 p.m. Annual MPhA Banquet—Awards and Prizes. Special Guest—Charles West, Executive Vice President NARD.



Thursday June 27 9:30 a.m. Special C.E. Program—Simon Solomon Seminar by William Skinner, P.D., J.D.

June 23–27, 1985 Carousel Hotel, Ocean City, Maryland 103rd Annual Convention of the Maryland Pharmaceutical Association in conjunction with the Delaware Pharmaceutical Society Call (301) 727-0746 for more details.



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The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Cromwell Bridge Road Beltway Exit No. 29. For further information contact President Frank Block (phone: 358-2743). This organization has several veteran pharmacists available for part-time employment.

Pharmacy Owner: Have you got the HMO & Mail Order Blues? Thinking about selling, want top dollar. Freedom Drugs wants to expand. Contact: Harvey Goldberg-242-1441 or 485-4500.

Rx Competitive Pricing Survey: Be profitable and improve pharmacy image. Rx Competitive pricing survey of top five major Baltimore Chains. Subscribing rate is \$60.00 for 6 survey (bi monthly) or \$15.00 each issue. Send check or money order to Freedom Drugs-TIPS (Tools to Increase Productive) 3903 Hollins Ferry Road, Baltimore, Maryland 21227.



May 23 (Thurs.)—Alumni Association Graduation Banquet: Eudowood.

June 2-6—American Society of Hospital Pharmacists annual meeting, Reno, NV.

June 14-15—MSHP Seminar: Host Farms, Lancaster, PA.

June 23-27—MPhA CONVENTION IN OCEAN CITY—SUN, SAND, SURF, DON'T MISS OUT, PLAN TO ATTEND.

July 4-11—American Association of Colleges of Pharmacy annual meeting, San Francisco, CA.

July 31-Aug 4—American College of Apothecaries annual meeting, San Francisco, CA.

October 20-24—National Association of Retail Druggists annual meeting, New York, NY.

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

Dear Association Director:

In an effort to update your association with the activities of the PADA Foundation, I have enclosed an article entitled "Pointers For Parents" which has run in many newspapers across the country. Please feel free to publish this article in your association's newsletter or journal.

The article answers many common questions parents have about drug abuse, and can provide your pharmacists with better awareness and understanding of the drug problem. If any of your pharmacists are interested in submitting this article to local newspapers, they can contact the PADA Foundation at 1-800-222-PADA for reprints. Any exposure that PADA receives heightens awareness of the seriousness of the drug problem in our country and expands the pharmacists involvement in the program.

Sincerely, Lori Gosset

Pointers For Parents CAN YOU SPOT A KID

WHO'S INTO DRUGS?

Right now, experts say, more than one-third of all kids in America use illegal drugs. One out of every 18 high school seniors is using marijuana every day. How can parents know if their child is one of

Pharmacists Against Drug Abuse (PADA), an innovative anti-drug abuse program designed to educate the public through local community pharmacists, offers these tips:

- · Look for changes in behavior and appearance.
- · School grades may suddenly start to drop.
- tivities.
- drawal from family and friends program. and a tendency to "hang out" with new friends you're not invited to meet.
- Obvious signs include bloodshot eyes and persistent sweet, lingering odor on cloth-

PADA was organized through the efforts of McNeil Pharmaceutical and the Johnson & Johnson Family of Companies. throughout the country. The 1-800-554-KIDS.



Your pharmacist can be a good source of information about drug abuse among youngsters.

There's a loss of interest White House Drug Abuse Polin things that were important, icy Office, ACTION, PRIDE and such as sports or other ac- the National Federation of Parents For Drug-Free Youth • There may be a with- (NFP) are supporting the

> PADA spokesmen emphasize the importance of parent involvement in this campaign, the need for them to know about drugs, to talk to their kids, to get involved in community organizations that can turn around the drug problem and drug culture in America.

Ask your pharmacist about The resulting public service the free PADA informational campaign will use the re-brochures and other informabrochures and other informasources of some 120,000 phartion or call ACTION/PRIDE at macists at 55,000 pharmacies 1-800-241-7946 or the NFP at



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THE MARYLAND PHARMACIST

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June, 1985 Vol. 61 No. 6



1985 Legislative Wrap-Up

Psoriasis and its Treatment with OTC Remedies

— Thomas A. Gossel — J. Richard Wuest

This and That About Pharmacy

— Leon Weiner

The Asthma-Aspirin Sensitivity Link

Hospital Pharmacy Infusions

— Gregory P. Wedin

Abstracts

Annual MPhA Convention (Joint with Delaware) June 23-27, 1985 Ocean City, Maryland, Be There!!

THE MARYLAND PHARMACIST

BALTIMORE MARYLAND 21201

650 WEST LOMBARD STREET TELEPHONE 301/727-0746

JUNE, 1985

VOL. 61

NO. 6

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A DAY OFF?

So you want the day off. Let's take a look at what you are asking for. There are 365 days per year available for work. There are 52 weeks per year in which you have two days off per week, leaving 261 days available for work. Since you spend 16 hours each day away from work, you have used up 170 days, leaving only 91 days available. You spend 30 minutes each day on coffee break leaving only 68 days available. With a one hour lunch period each day, you have used up another 46 days leaving only 22 days available for work. You normally spend 2 days per year on sick leave. This leaves you only 20 days available for work. We are off for 5 holidays per year, so your available working time is down to 15 days. We generously give you 14 days vacation per year which leaves only 1 day available for work.

And I'll be darn'd if you're going to take that day off!!!

author unknown

Ronald A. Sanford, P.D.

PRESIDENT 1984-85.

1985 Legislature Wrap-up

The work of the Maryland Pharmaceutical Association in the area of government relations is perhaps the most vital function of the Association on behalf of all pharmacists; whether they are members or not. It is true, unfortunately, that even non-members of the Association benefit whenever the Association is successful in its lobbying efforts to the extent that the practice of pharmacy is enhanced for all pharmacists. The Association in effect represents all pharmacists when testimony is presented before legislative committees, when interviews are conducted with the news media, and when position papers are provided to important government agencies.

The Association works in cooperation with a number of other lobbying groups such as the Medical Society, the Dental Association, the Nurses Association and several other allied health care professions. The MPhA also works with manufacturing interests, the Association of Chain Drug Stores, insurance companies, proprietary and business interests and others. As the Association begins to formulate a position on specific legislative issues, it coordinates its views and testimony with several other groups within the profession of pharmacy such as the Board of Pharmacy, the School of Pharmacy, the Maryland Society of Hospital Pharmacists, the Maryland Chapter of the American Society of Consulting Pharmacists, the Pharmacy Guild and others to ensure that the voice of Pharmacy can be presented in as unified fashion as possible.

The responsibility for legislative activity is conducted by the Legislative Committee, under the Chair of Milton Sappe. Working with the Executive Director, David Banta, who is also the Association's registered lobbyist, the Committee gets its general policy direction from appropriate resolutions from the House of Delegates. Early each Fall, the Committee suggests a legislative platform of positions on issues and proposed bills which is then subsequently ratified by the Board of Trustees. The Committee monitors the legislative process while the General Assembly is in session and makes decisions regarding revised policy as the

need develops and situations change. Banta monitors the activity of the legislature on a daily basis during the session. He develops, coordinates and presents testimony on the bills that are heard before legislative committees, including the presentation of position papers when necessary. Occasionally, pharmacists, usually from the Legislative Committee, are called upon to provide expert testimony on certain bills of a technical nature. Certain larger issues will call for a major showing of pharmacy support or opposition in the form of multiple witnesses or an organized telephone and letter campaign. These activities are coordinated by the Legislative Committee.

The results of the work of the Legislative Committee is reported back to the membership in the Newsletter during the session and as a Committee report at the Annual Convention. Over the past several years, the Association has been very successful in full-filling its legislative goals while utilizing a maximum efficiency in expenditure of Association resources. This past year was very productive for the Committee. Of course the Governor must sign into law each of the bills which passed the legislative process and they will not take effect until July 1, 1985 in most cases. Below is a summary of the major bills which were worked on and followed by the Association this year.

Mandatory Continuing Education

An ACT concerning

Pharmacists—Continuing Pharmaceutical Education FOR the purpose of requiring a licensed pharmacist to submit to the State Board of Pharmacy certain evidence of compliance with continuing education requirements before renewal of a license; prohibiting the Board from renewing a pharmacist's license and issuing a certificate of renewal if certain conditions are not met; providing certain exceptions; allowing the Board to evaluate and approve programs of continuing pharmaceutical education; specifying the form and content of the continuing pharmaceutical education programs; requiring certain standards for the programs; providing for the



approval of certain continuing pharmaceutical education programs; providing for evidence of completion of the program; allowing the Board to adopt regulations to carry out this Act; and generally relating to continuing pharmaceutical education.

BY repealing and reenacting, with amendments, Article—Health Occupations

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law. Underlining indicates amendments to bill. Strike-out indicates matter stricken from the bill by amendment or deleted from the law by amendment.

SENATE BILL No. 754

Section 12-308
Annotated Code of Maryland
(1981 Volume and 1984 Supplement)
BY adding to

Article—Health Occupations Section 12-308.1 Annotated Code of Maryland (1981 Volume and 1984 Supplement)

Preamble

WHEREAS, The General Assembly recognizes that the health and welfare of the citizens of this State depend to a great extent upon the skill and knowledge of licensed pharmacists; and

WHEREAS, To advance the state of professional and scientific knowledge and to assure the continuing competency of licensed pharmacists, the General Assembly recognizes the need for continuing education in all aspects of the professional practice of pharmacy; now, therefore.

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article—Health Occupations

12-308.

- (a) Unless a license is renewed for a 2-year term as provided in this section, the license expires on the first September 30 that comes after the effective date of the license.
- (b) At least 1 month before the license expires, the Board shall send to the licensee, by first class mail to the last known address of the licensee, a renewal notice that states:
- (1) The date on which the current license expires;
- (2) The date by which the renewal application must be received by the Board for the renewal to be issued and mailed before the license expires; and
 - (3) The amount of the renewal fee.
- (c) Before the license expires, the licensee periodically may renew it for an additional 2-year-term, if the licensee:



- (1) Otherwise is entitled to be licensed;
- (2) Pays to the Board a renewal fee of \$50; and
- (3) Submits to the Board:
- (I) [a] A renewal application on the form that the Board requires; AND
- (II) SATISFACTORY EVIDENCE OF COMPLIANCE WITH THE CONTINUING EDUCATION REQUIREMENTS SET UNDER THIS SUBTITLE FOR LICENSE RENEWAL.
- (d) The Board shall renew the license of and issue a renewal certificate to each licensee who meets the requirements of this section.

12-308.1.

- (A) EXCEPT AS PERMITTED IN SUBSECTIONS (B) AND (C) OF THIS SECTION, THE BOARD MAY NOT RENEW THE LICENSE AND ISSUE A CERTIFICATE OF RENEWAL TO ANY PHARMACIST UNTIL THE PHARMACIST PRESENTS EVIDENCE OF HAVING COMPLETED 30 HOURS OF APPROVED CONTINUING PHARMACEUTICAL EDUCATION WITHIN THE PRECEDING 2 YEARS.
- (B) THE BOARD MAY RENEW THE LICENSE AND ISSUE A CERTIFICATE OF RENEWAL TO A PHARMACIST WHO PRESENTS ACCEPTABLE EVIDENCE THAT THE PHARMACIST WAS UNABLE TO COMPLY WITH SUBSECTION (A) OF THIS SECTION DUE TO CIRCUMSTANCES BEYOND THE PHARMACIST'S CONTROL.
- (C) THE BOARD MAY RENEW THE LICENSE AND ISSUE A CERTIFICATE OF RENEWAL FOR THE FIRST RENEWAL PERIOD FOLLOWING THE ISSUANCE OF THE ORIGINAL LICENSE WITHOUT REQUIRING A PHARMACIST TO COMPLETE ANY CONTINUING PHARMACEUTICAL EDUCATION, IF THE PHARMACIST OBTAINS A LICENSE WITHIN 1 YEAR OF THE COMPLETION OF THE PHARMACIST'S PHARMACEUTICAL EDUCATION.
- (D) THE BOARD SHALL EVALUATE AND APPROVE PROGRAMS OF CONTINUING PHARMACEUTICAL EDUCATION SUBMITTED TO THE

BOARD BY THE PERSON WHO INTENDS TO OFFER THE PROGRAM.

(E) EACH PROGRAM OF CONTINUING PHARMACEUTICAL EDUCATION SHALL CONSIST OF AT LEAST 1 CONTINUING EDUCATION UNIT, WHICH IS 1 HOUR OF PARTICIPATION IN AN ORGANIZED CONTINUING EDUCATIONAL EXPERIENCE, INCLUDING POSTGRADUATE STUDIES, INSTITUTES, SEMINARS, LECTURES, CONFERENCES, WORKSHOPS, CORRESPONDENCE COURSES, CASSETTE PROGRAMS, PROGRAMMED LEARNING COURSES, AUDIOVISUAL PROGRAMS, AND ANY OTHER FORM OF PRESENTATION THAT IS APPROVED BY THE BOARD.

(F) ANY ASPECT OF THE PRACTICE OF PHARMACY MAY BE THE SUBJECT OF A PROGRAM OF CONTINUING PHARMACEUTICAL EDUCATION, INCLUDING PHARMACEUTICS (COMPOUNDING), PHARMACOLOGY, PHARMACEUTICAL CHEMISTRY, BIOCHEMISTRY, PHYSIOLOGY, MICROBIOLOGY, PHARMACY ADMINISTRATION, AND PROFESSIONAL PRACTICE MANAGEMENT.

(G) EACH PROGRAM OF CONTINUED PHAR-MACEUTICAL EDUCATION SUBMITTED TO THE BOARD OF PHARMACY FOR APPROVAL SHALL:

(1) HAVE A DEFINITE STATED OBJECTIVE:

(2) BE PRESENTED IN AN ORGANIZED MANNER BY A QUALIFIED INSTRUCTOR OR RESOURCE PERSON; AND

(3) INCLUDE A METHOD OF PROGRAM EVALUATION THAT IS SUITABLE TO THE TYPE OF PROGRAM BEING PRESENTED.

(H) EACH PERSON WHO OFFERS A PROGRAM OF CONTINUING PHARMACEUTICAL EDUCATION SHALL:

(1) PROVIDE A MEANS FOR REGISTRATION BY THE PARTICIPANTS;

(2) MAINTAIN A RECORD OF PARTICIPA-

TION FOR AT LEAST 3 YEARS; AND

(3) FURNISH EACH PARTICIPANT WITH ADEQUATE DOCUMENTATION OF SATISFACTORY COMPLETION OF THE PROGRAM, INCLUDING:

(I) THE NAME OF THE PARTICIPANT;

(II) THE NAME OF THE SPONSOR;

(III) THE TYPE OF PROGRAM COMPLETED;

(IV) THE NUMBER OF CONTINUING ED-UCATION HOURS OR UNITS COMPLETED; AND (V) THE DATE OF COMPLETION.

(I) FOR PURPOSES OF EVALUATION, MEMBERS OF THE BOARD MAY ATTEND AND PARTICIPATE IN ANY CONTINUING PHARMACEUTICAL EDUCATION PROGRAM APPROVED FOR CREDIT.

(J) A PHARMACIST WHO COMPLETES A PROGRAM OF CONTINUING PHARMACEUTICAL EDUCATION THAT IS NOT PREVIOUSLY APPROVED BY THE BOARD MAY REQUEST THE BOARD, IN WRITING, TO APPROVE THE PROGRAM FOR CREDIT.

(K) THE BOARD SHALL ADOPT REGULATIONS THAT ARE NECESSARY TO CARRY OUT

THE PURPOSES OF THIS SECTION.

(L) ANY CONTINUING EDUCATION PROGRAM THAT IS CURRENTLY APPROVED BY THE AMERICAN COUNCIL ON PHARMACEUTICAL EDUCATION AUTOMATICALLY QUALIFIES FOR CONTINUING EDUCATION CREDIT.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 1985 1986.

Regulation of PPO's

AN ACT concerning

Health Insurance—Preferred Provider Policies or Preferred Provider Contracts

FOR the purpose of permitting the offering and administration of preferred provider health insurance policies or insurance contracts, subject to the approval of the Insurance Commissioner, to providers of health care services; providing for the terms and conditions of preferred provider health insurance policies or insurance contracts; providing that under certain circumstances payment of services rendered by nonpreferred providers may not be less than a certain amount; exempting employee benefit plans regulated by federal law or by the Employee Retirement Income Security Act of 1974 (ERISA); and generally relating to preferred provider health insurance policies and insurance contracts.

By adding to

Article 48A—Insurance Code Section 354CC, 470V, and 477CC Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law. Underlining indicates amendments to bill. Strike-out indicates matter stricken from the bill by amendment or deleted from the law by amendment.

354CC.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "PREFERRED PROVIDER POLICIES OR PREFERRED PROVIDER CONTRACTS" MEANS INSURANCE POLICIES OR INSURANCE CON-TRACTS WHICH SPECIFY THE SERVICES AND HOW SERVICES ARE TO BE COVERED WHEN RENDERED BY PREFERRED AND NONPREFERRED PROVIDERS.

- (3) "PREFERRED PROVIDER" MEANS A PROVIDER WHO HAS CONTRACTED WITH A NONPROFIT HEALTH SERVICE PLAN TO MEET THE TERMS AND CONDITIONS OFFERED IN THE PREFERRED PROVIDER POLICY OR PREFERRED PROVIDER CONTRACT.
- (4) "PROVIDER" MEANS ANY PERSON, INCLUDING A PHYSICIAN OR HOSPITAL, WHO IS LICENSED OR OTHERWISE AUTHORIZED TO PROVIDE HEALTH CARE SERVICES, WITHIN THE SCOPE OF THE LICENSE OR AUTHORIZATION.
- (5) "NONPREFERRED PROVIDER" MEANS A PROVIDER ELIGIBLE FOR PAYMENT UNDER A PREFERRED PROVIDER POLICY OR PREFERRED PROVIDER CONTRACT, WHO IS NOT A CONTRACTEE UNDER THE PROVISIONS OF THE INSURANCE POLICY OR INSURANCE CONTRACT.
- (6) "UNFAIR DISCRIMINATION" MEANS ANY ACT, METHOD OF COMPETITION, OR PRACTICE ENGAGED IN BY A NONPROFIT HEALTH SERVICE PLAN, WHICH IS PROHIBITED BY SECTIONS 217 THROUGH 234, INCLUSIVE, OF THIS SUBTITLE OR ANY ACT, METHOD OF COMPETITION, OR PRACTICE NOT SPECIFIED IN SECTIONS 217 THROUGH 234, INCLUSIVE, THAT THE COMMISSIONER BELIEVES IS UNFAIR OR DECEPTIVE AND WHICH RESULTS IN THE INSTITUTION OF AN ACTION BY THE COMMISSIONER UNDER SECTION 216 OF THIS SUBTITLE.
- (B) (1) SUBJECT TO THE APPROVAL OF THE COMMISSIONER, A NONPROFIT HEALTH SERVICE PLAN MAY OFFER OR ADMINISTER A HEALTH BENEFIT PROGRAM UNDER WHICH THE NONPROFIT HEALTH SERVICE PLAN MAY OFFER PREFERRED PROVIDER POLICIES OR PREFERRED PROVIDER CONTRACTS THAT LIMIT THE NUMBERS AND TYPES OF PROVIDERS OF HEALTH CARE SERVICES ELIGIBLE FOR PAYMENT AS PREFERRED PROVIDERS UNDER THE INSURANCE POLICIES OR INSURANCE CONTRACTS.
- (2) A NONPROFIT HEALTH SERVICE PLAN MAY ESTABLISH TERMS AND CONDITIONS THAT SHALL BE MET BY A PROVIDER IN ORDER TO QUALIFY FOR PAYMENT AS A PREFERRED PROVIDER UNDER THE INSURANCE POLICIES OR INSURANCE CONTRACTS.
- (3) IF A PREFERRED PROVIDER POLICY OR PREFERRED PROVIDER CONTRACT PROVIDES FOR REIMBURSEMENT FOR ANY SERVICE THAT IS WITHIN THE LAWFUL SCOPE OF PRACTICE OF A HEALTH CARE PROVIDER LI-

CENSED UNDER THE HEALTH OCCUPATIONS ARTICLE, ANY PARTICIPANT, BENEFICIARY, OR OTHER PERSON COVERED BY THE INSURANCE POLICY OR INSURANCE CONTRACT SHALL BE ENTITLED TO REIMBURSEMENT FOR THAT SERVICE.

- (4) PREFERRED PROVIDER POLICIES OR PREFERRED PROVIDER CONTRACTS OFFERED UNDER THIS SECTION SHALL PROVIDE FOR PAYMENT OF SERVICES RENDERED BY NON-PREFERRED PROVIDERS. UNLESS THE NON-PROFIT HEALTH SERVICE PLAN DEMON-STRATES TO THE SATISFACTION OF THE IN-COMMISSIONER **SURANCE THAT** AN ALTERNATIVE LEVEL OF PAYMENT IS MORE APPROPRIATE UNDER THE CIRCUMSTANCES. ANY PAYMENT MADE UNDER THIS PARA-GRAPH MAY NOT BE LESS THAN 80% OF THE AVERAGE PAYMENTS AMOUNT THAT WOULD HAVE BEEN PAID TO PREFERRED PROVIDERS FOR SIMILAR SERVICES IN THE SAME GEO-GRAPHIC AREA.
- (C) IF THE RATES FOR EACH INSTITUTIONAL PROVIDER UNDER A PREFERRED PROVIDER POLICY OR PREFERRED PROVIDER CONTRACT VARY BASED UPON INDIVIDUAL NEGOTIATIONS, GEOGRAPHIC DIFFERENCES, OR MARKET CONDITIONS AND ARE APPROVED BY THE HEALTH SERVICES COST REVIEW COMMISSION, THE RATES MAY NOT BE DEEMED TO CONSTITUTE UNFAIR DISCRIMINATION UNDER THIS ARTICLE.
- (D) THIS SECTION DOES NOT APPLY TO ANY EMPLOYEE BENEFIT PLAN REGULATED BY FEDERAL LAW OR BY THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974 (ERISA).

OTHER BILLS. The Association defeated legislation which would have required the listing of all inactive ingredients of prescription drugs on the prescription label (HB 1476), one which would have required that pharmacists list the date beyond which a drug loses its potency in addition to the expiration date (HB 131) and one which would have required all controlled substances to have a triplicate prescription form so that one part could be mailed to the Division of drug control for monitoring (HB 1515). The Association failed to pass two bills guaranteeing freedom of choice for participation with all HMO's (SB 722 and HB 669). However, the introduction of these bills alone has resulted in equal access for all pharmacies to participate in most Maryland HMO's. The Association carefully monitored all health care cost containment legislation for impact upon the profession. After screening over 3,000 bills introduced in the 1985 session, the Legislative committee and Lobbyist consider this to be another successful session for the lobbying effort on your behalf. Contact the office if you have any questions regarding the 1985 General Assembly session.

SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 4

Counseling Consumers on Psoriasis and Its Treatment with OTC Remedies

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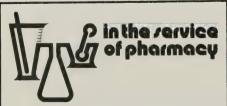
Goals

The goals of this lesson are to:

 discuss the etiology and treatment of psoriasis;

review the pharmacology and therapeutics of OTC products used to treat it;

 distinguish psoriasis from other disorders that produce similar symptoms.



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Objectives

At the completion of the lesson, the successful participant will be able to:

choose the appropriate OTC agent for treating psoriasis;

2. explain the proper technique for applying it;

3. decide when the patient should be referred to a specialist.

One to three percent of Americans are reportedly afflicted with psoriasis. Based on the total population of the U.S., this might not be considered a large number of people. However, to those individuals who must contend with the "heartbreak of psoriasis," it is an extremely serious disorder. Visible plaques on the scalp, face, hands, or arms, or more widely spread over the body may cause them to avoid contact with the public and become virtual recluses.

Many OTC products effectively control the symptoms of psoriasis, as do several drugs that require a prescription (e.g., methotrexate, methoxsalen, anthralin). Pharmacists often interact with those patients who seek relief from their symptoms.

There are two other conditions that appear similar to psoriasis — seborrheic dermatitis and severe dandruff. Both cause symptoms that may be easily confused with psoriasis.

This month's lesson examines psoriasis from the standpoint of identifying important aggravating factors and major symptoms, and discussing rational treatment with OTC remedies. Specific attention is directed toward distinguishing psoriasis from other disorders that produce similar symptoms. Advice for consumers who purchase OTC remedies for treating psoriasis is also presented.

Background and Symptoms

The biblical term "lepra" described a series of skin diseases that

included the disorder we now call psoriasis. The association was common until the 1840's when the term was abandoned in describing psoriasis. One wonders how many people had experienced psoriasis, and because of their lesions, were needlessly shunned as being "unclean" by friends and family who believed they were lepers.

The disorder is, fortunately, relatively uncommon in America. However, the incidence of one to three percent may be a low estimation because many persons with mild conditions self-treat their symptoms without benefit of medical advice.

Psoriasis is a chronic inflammatory condition of the skin, characterized by well-defined pink or dull red lesions that have distinctive borders. These are covered with thick silvery colored scales. If these scales are removed, they become powdery and the underlying skin may bleed in numerous spots. This phenomenon is referred to as Auspit's sign. While some sufferers exhibit constant scaling associated with itching and discomfort, others may experience vari able periods of remission. Chronic itching is the most characteristic symptom, noted in over eighty per cent of patients.

Psoriatic persons frequently have a greater than normal intolerance to cold weather. This is due to in creased vasodilation and capillar proliferation which promotes a morrapid than normal loss of body heat

Psoriasis is mainly a disease c Caucasians; ninety-eight percent c all sufferers are Caucasian. Both me and women experience it to the sam extent. Psoriasis may manifest as single lesion confined to an elbow c the scalp, or it may be found all ove the body (Figure 1).

Psoriasis shows no prevalence t socioeconomic class or education. is slightly more common in th northeast and north central state

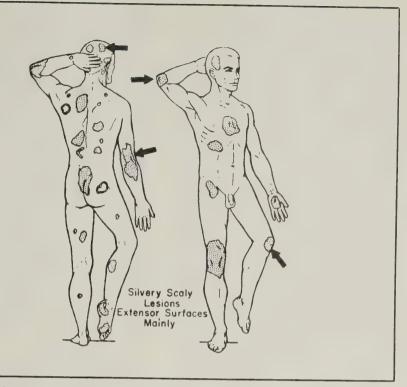


Figure 1. Distribution of psoriatic lesions. From: Sauer GC: Manual of Skin Diseases 3rd Ed, J.B. Lippincott Company, 1973.

oriatic lesions most commonly apar around age 30, but may emerge thin the first year of life or not unold age. The condition is not congious.

The term psoriasis vulgaris decibes a condition resulting from leans that coalesce into large, usual-symmetrical areas. These are most mmonly seen on the elbows, knees d lower back.

iology

Psoriasis is characterized by alterons in the epidermis, which lead rapid turnover of cells, along with elling of the underlying capillas. Recall that the skin is composed two major layers, the dermis and dermis. The dermis (lower layer) itains a rich vascular system ich supplies nutrients to all layof the skin. The epidermis ("epi" outer), in turn, is comprised of major strata, neither of which its own blood supply. The basal wer) level of the epidermis lies ditly on top of the dermis, and is l provided with all its nutritional ds from fluids that diffuse uprd from the dermis.

he cells that comprise the epiderare continually formed at the ba-

sal level. Young cells migrate upward toward the skin's surface. Because there is insufficient nutrition to sustain their life, they die approaching the surface and dehydrate. These highly compacted, dead, dried cells are collectively known as the keratin (stratum corneum) layer. With normal skin "wear and tear," replacement cells from underneath push upward and the outermost dead epithelial cells continually slough off. This process ordinarily requires three to four weeks for completion. In psoriatic conditions, however, this turnover rate changes to three to four days. As a result, both live and dead cells accumulate on the skin's surface to form the thickened, scaly patches that have the characteristic silvery appear-

Recent research into the condition has shown that psoriasis is genetic. A familial pattern is evidenced in approximately 30 percent of all patients. Genetic, susceptibility does not mean that psoriasis will automatically occur in the offspring of affected persons. For example, the condition is more likely to appear in both members of a set of identical twins than in both members of a fraternal pair. If one parent has psoria-

sis, the children have a twenty-five percent greater chance of developing it. If both parents are affected, the probability increases to sixty-five percent.

An alteration in the immune system also seems to play an important contributory role. For example, IgG levels can be detected in the skin of psoriatic lesions. IgG is the most important of the immunoglobins (antibodies) that are responsible for combatting infection and invasion by foreign protein material. One theory suggests that the individual loses his suppressant action on the immune system, and antibodies then form against skin antigens. This allows for formation of antigen-antibody complexes, a leukocyte response, and eventually the inflammatory lesions characteristic of psoriasis.

Numerous other theories have also been advanced as possible causes of the disorder. However, no single hypothesis explains all ramifications. At this time, the precise cause or causes remains unknown.

TABLE 1 Factors Reported to Provoke Psoriasis Attacks

Dermal lesions (e.g., cuts, burns, sunburns)

Internal streptococcal infections Sore throat

Drugs (e.g., antimalarials, lithium salts, beta-adrenergic blockers, clonidine, potassium iodide, gold compounds)

Endocrine (e.g., psoriasis often clears during pregnancy, and flares up in menopause)

Menopause)
Obesity
Emotional stress
Alcoholism
Sunlight* and weather extremes
Low humidity

*Exposure to moderate amounts of sunlight is associated with improvement of psoriasis. Too much exposure or sunburn is associated with psoriatic flare-ups.

Aggravating Factors. Factors that have been identified as possible causes of exacerbation of psoriasis are listed in Table 1. A distinguishing feature of psoriasis is the Koebner reaction. Briefly, this phenomenon involves the appearance of lesions at sites of dermal injury. Most injury is physical (e.g., cuts, scratches, acute sunburn), but any other injury may also elicit a psoriat-

ic response. The relationship between trauma and subsequent appearance of lesions is not clear. Most lesions appear within three to eighteen days of the initial trauma. Therefore, it is important that psoriatic patients avoid injury or trauma to their skin.

Scratching or picking at scales should be avoided or at least minimized. Use of adhesive tape should also be avoided. If it must be used, application should be done carefully and judiciously since its removal may stimulate a psoriatic lesion.

One thousand psoriatic sufferers responded to a questionnaire that requested information about the factors that made their conditions better or worse. Seventy-seven percent indicated that hot weather improved their condition, while twenty-three percent said it worsened it. Twelve percent indicated that cold weather made their condition worse.

Endocrine factors appear to play a role in inducing psoriatic flare-ups. Psoriasis often improves or worsens during pregnancy. It may recur or appear for the first time after child-birth. Emotional stress frequently aggravates psoriasis.

Throat infections as such are not known to cause psoriasis. However, an interesting note is that half the patients in a large study of persons who had developed psoriasis during childhood, had also suffered from a streptococcal infection that caused a sore throat immediately prior to the onset of their condition.

Distinguishing Psoriasis From Other Afflictions

The symptoms of psoriasis can be easily confused with those of seborrheic dermatitis or severe dandruff. However, there are certain features of each disorder that allow for reliable differentiation (Table 2).

Diagnosing psoriasis is aided further by examining the fingernails and toenails. In persons with psoriasis, the hyperproliferation of nail beds, abnormal growth of nail plates, and accumulated keratin under the nails produce distorted, thick, opaque, and crumbly nails. Pits and ridges in the nails are often seen. Separation of the free end of the nail from its bed becomes marked, and indeed, the nail may be completely lost. These nail changes are noted in about half of all psoriasis sufferers. While not a definitive indication of psoriasis, nail changes is one of several characteristics that help in differential diagnosis.

Treatment

There is a variety of OTC products that may be used by persons with psoriasis, but there is no specific cure for the disorder. The products are intended to reduce its severity and control the symptoms. Because the barrier which normally prevents drug penetration into the skin is disrupted, psoriatic skin may be more permeable than normal skin to many medications. In the early stages of treatment, the patient may, therefore, respond rapidly to a topically-

applied agent. The improvement rate then slows as the skin's barrier approaches the normal state. Such improvement is hindered, however, by the itching and discomfort which are more intense when the skin is rough, dry and thick. Psoriatic individuals have a difficult time ignoring the itching and overcoming the impulse to scratch the lesions.

The ingredients contained in OTC products that were suggested by ar FDA OTC advisory panel as being safe and effective for treating psoria sis are listed in Table 3. The pane advised that only mild cases of pso riasis should be self-treated, and tha individuals affected with recalci trant psoriatic lesions or those occur ring over large areas of their body should be referred to a physician fo treatment.

TABLE 3
Safe and Effective OTC Ingredients for
Treating Psoriasis*

Coal Tar Preparations (coal tar, coal tar distillate, coal tar extract, coal tar solution, crude coal tar extract, crude tar extract, extract of coal tar, extract of coal tar, extract of coal tar, extract of coal tar, solution, liquor carbonis detergens, refined extract of coal tar, solutilized coal tar extract, solutilized crude coal tar, standardized extract of coal tar, standardized tar extract)

Salicylic Acid

*ingredients classified in Category I by FDA's Advisory Review Panel on OTC Miscellaneous External Drug Product

TABLE 2
Distinguishing Features of Dandruff, Seborrhea and Psoriasis

Distinguishing Features of Dandrull, Seportnea and Fsortasis							
Characteristic	Dandruff	Seborrheic Dermatitis	Psoriasis				
Site	Scalp	Scalp, face, and body (especially hairy areas, body folds, and behind ears.)	Scalp and body (especially knees, elbows, low back, nails)				
Borders Inflammation Appearance of scales	Indistinct No Dry, grayish-white	Indistinct Yes Greasy	Very sharp Yes Silvery scales which flake off in layers				
Age of onset	Puberty	Puberty	Young adulthood, as a rule, but can occur at any age				
Itching	Variable	Usual	Variable				
External factors that worsen condition	Cold weather	Stress, poor health	Stress, mechanical irritation. Also see Table 1				
Rate of epidermal turnover	2X above the norm	More than 2X above the norm	Greatly increased above the norm (10-20X)				
Duration	Can persist for life, diminishing in middle and old age	Can persist for life, frequent exacerbations and remissions	Can persist for life; exacerbations and remissions				

The panel specifically noted that reatment of psoriasis requires a form f therapy different than that for danruff or seborrhea. However, if the ondition is not accurately diagosed and anti-dandruff or anti-eborrhea therapy is used, no harm likely to follow. The psoriasis will robably persist, but it will not worsa. However, the consumer is wasting both time and money.

Coal Tar Preparations. Various roducts containing coal tar derivaves have been used to treat psorias for over a century. Today, they acount for the largest share of the OTC soriasis remedies sold in the U.S. - a market value reported to exceed 100 million each year.

Several different sources of tar ive been used in previous years. Inday, however, the most widely sed tar preparations for controlling soriasis (as well as dandruff and borrheic dermatitis) are those deved from coal tar. It has not been sown that tars from various sources ake a difference in the therapeutic tivity of the final product. In fact, ere is still little agreement as to the tual composition of coal tar.

To complicate matters further, anufacturers have attempted to reie it into more cosmetically acceptle fractionates, distillates, solums, filtrates and tinctures. They ve reduced its disagreeable physil properties even more by comunding coal tar products into ampoos, gels, lotions, bath oils d liniments. Any one of these prosses may modify both the therautic activity and safety profiles of al tar. Thus, the final product is bably qualitatively and quantitaely different from other products at contain coal tar prepared by ernate means.

Coal tar is believed to act as a costatic agent, i.e., it inhibits cell production. Or, it may act as a catolytic, penetrating the epiders and helping to remove the scales oduced in psoriasis. Its action may on be as simple as providing antiposis through its phenolic content. e exact mode of action is not yet town.

Consumers should be reminded t coal tar preparations may stain thing, skin, and hair (especially y, blond, or bleached). Coal tar parts a characteristic odor so it should be thoroughly washed out before going out in public.

Coal tar is suspected of being carcinogenic and, indeed, chronic exposure to coal tar derivatives over several decades has been shown to be linked to cancer. The FDA advisory panel concluded that coal tar correctly applied to the scalp for treating dandruff was present on the skin for such a short period of time (e.g., five to twenty minutes maximum, one to three times weekly). that it was safe for short term selfadministration for dandruff control. However, since a drug product applied to the body to treat psoriasis and seborrhea may remain in contact with the skin for longer periods, additional studies to clarify coal tar's carcinogenic potential are needed before a final ruling can be made. The panel recommended that coal tar products remain available OTC while these studies are underway. Representative coal tar-containing products are listed in Table 4.

Keratolytics. Only salicylic acid was approved by the advisory panel

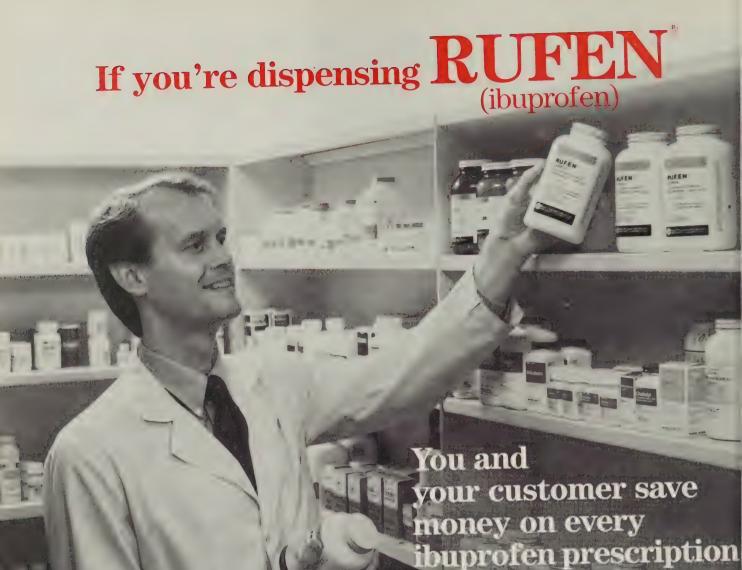
as a safe and effective OTC antipsoriatic keratolytic agent. The panel believed that keratolytics act by dissolving the cement that holds epidermal cells together, rather than dissolving keratin itself. Keratolytics loosen the scales, enabling them to be gently rubbed free and washed off more readily. The exact mechanism for this action is not known, but it is thought to result from lowering the pH in the area. This causes the epidermal cells to become hydrated from accumulation of endogenous fluid. The scales swell, soften and shed. Keratolytics do not prevent the scales from being formed.

Sulfur and resorcinol, two keratolytics approved for other skin conditions such as acne, are *not* indicated for treating psoriasis. They were, therefore, not reviewed by the advisory panel. Both substances may remain on the OTC market indicated for their other uses.

Corticosteroids. Corticosteroids possess mild anti-itching action, but have a more marked anti-inflammatory effect. Hydrocortisone

TABLE 4
Representative OTC Products for Relief of Psoriasis

Product	Dosage Forms								
	Bath Additive	Cream	Gel	Lotion		Shampoo	Soap		
Alphosyl		X		x		poo	Вопр		
Balnetar	x						-		
Cutar	х						-		
Denorex			х	х		Х			
DHS Tar						х			
Doak	х			х	х				
Duplex T						х			
Estar			х						
Iocon						X			
Lavatar	x								
Neutrogena/T						x			
Oxipor				x					
Packer's Pine Tar						х	x		
Pentrax Tar						X			
Polytar	х					X			
Pragmatar					х				
Psorex						х			
Psor Gel			x						
Tarlene				x					
Tegrin		х		х		х			
Tersa-Tar						х			
Zetar	x					x			



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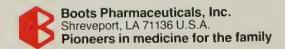
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products, therefore, have been suggested for OTC use in treating dandruff, seborrheic dermatitis, and osoriasis of the body and scalp along with many other uses (see "Couneling Consumers on Dermatitis and ts Treatment"). While the OTC adviory panel that reviewed it agreed hat topical hydrocortisone was safe, t also believed that the temporary elief of itching does not effectively control" any of these conditions. Effective treatment should involve ontrol of the excessive shedding of pidermal cells. The panel, thereore, recommended that corticosteoids need additional study to show roof of effectiveness.

On the prescription side of the edger, the fluorinated corticostebids are widely used and quite efective in ameliorating a wide variety of dermatological conditions in any patients. However, because of heir greater potential for systemical de effects (fluorinated steroids are such more readily absorbed than ydrocortisone), especially when he skin occluded after application, heir use requires physician supervi-

Emollients and Moisturizers. athing each day for thirty minutes ith an oil emollient usually affords le psoriatic person symptomatic reef from itching and dry skin. Bath ater should be comfortably warm it not too hot. Bathing with an nollient also softens the skin and elps remove the thick scales so that obsequently applied medications in more easily penetrate the skin. irthermore, removing these scales ith a washcloth improves the indidual's physical appearance and ental attitude. It also reduces the ctim's temptation to pick them off, activity associated with bleeding d secondary infection. Representive OTC emollient bath additives e listed in Table 5.

Other products that contain roisturizing agents which help the sin to preserve moisture are used tween bathings. Like emollient thing products, these products

TABLE 5 Representative OTC Emollient Bath Additives

Alpha Keri
Aveeno Colloidal Oatmeal
Aveeno Oilated
Bath-O-Vel
DOB
Domol
Jer-Bath
Kerasol
Lubath
LubraSol
Nutraderm
NutraSpa
Pedi-Bath
RoBathol
Ultra-Derm

help relieve itching and remove scales. The key word here is emollient. Simply bathing in plain water can potentially worsen the condition because water can dry the skin. Keratin does need moisture, but some other substance (i.e., an emollient) is needed to slightly occlude the area and hold the water on the skin.

Consumer Advice

Advising consumers on the self-treatment of psoriasis involves empathetic understanding of the condition. There is no absolute "cure". The only definitive treatment to date involves products that have the potential for causing toxicity to the extent that they are only available under medical supervision. In many persons with mild, uncomplicated psoriasis, especially that which remits from time to time, OTC products can lessen the severity of symptoms and make the condition more bearable.

If this constitutes adequate relief for the individual, the relatively nontoxic OTC products will be suitable. If the person is not satisfied with this, or if the condition worsens, he should seek the advice of a specialist in dermatology. Some rather remarkable results are being reported with the use of the prescription-only antipsoriatic therapies such as fluorinated topical corticosteroids with occlusion, oral methotrexate, and PUVA (psoralens with ultraviolet light — "A" wave length).

As far as the use of OTC products is concerned, strict compliance is needed for the medication to provide effective relief. Consumers should carefully read, understand, and follow directions. Daily use is recommended for most products.

In some instances, the creams, gels, lotions or ointments are to be applied several times a day and/or at bedtime. If the scalp is involved, medicated shampoos are recommended for morning use. Some manufacturers advise that shampoos should be massaged throughout the scalp area into a rich lather, and be allowed to remain on the scalp for a few minutes before rinsing. If the product's odor is offensive, a bland shampoo can be applied after the medicated product has been removed. A fine-tooth comb may be useful in removing scales from the scalp.

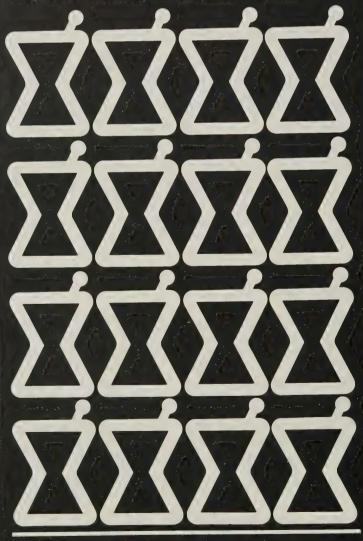
When treating psoriatic areas on the body, the medication should be gently massaged into the lesion to loosen and remove crusts and scales. The massaging should be firm but not so hard that the skin is broken. A hot bath prior to application of the medication may be helpful in removing scales.

These general precautions should be heeded: 1) avoid contact of the medication with the eyes and other mucous membranes, 2) discontinue use and contact a physician if irritation and worsening of the condition occurs.

A Note From The Editor

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This and That About Pharmacy

by Leon Weiner, P.D.

Spotlight on Irvin Goodman

IRVIN GOODMAN Southern High School "Smoke" Phi Alpha 2200 Bryant Avenue

Class Vice-President 1; Mixer Committee 3, 4; Terra Mariae 1, 2, 3, 4; Class President 3, 4; Softball 2; Basketball 1, 2; Junior Prom Committee 3; Senior Prom Committee 4.

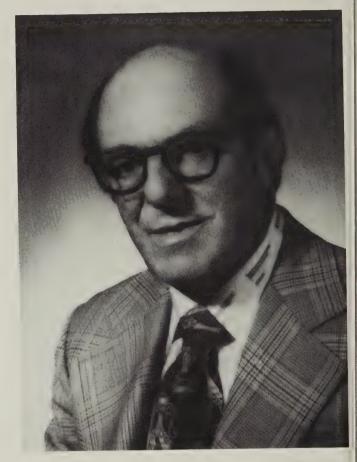
"Irv has shaped the destiny of our class for four years. 'Smoke' is one of the best liked fellows we know. Never has he refused to help anyone even when assistance seemed impossible."

Above are the comments made about Irv in his 1945 Pharmacy yearbook. Notice that it is still all true today.

In November 1984, Irvin Goodman, P.D., was inducted into the Jewish Educational Alliance (J.E.A.) Hall of Fame. This did not surprise anyone as Irv has been very active most of his life. When he was a youngster living in South Baltimore, his favorite sport was basketball. He played many years for Southern High School, The "Cavalier" Club at the J.E.A., "White Coffee Pot" in the Baltimore City League and then for the Maryland School of Pharmacy team under the coaching of Professor Ben Allen.

Dr. Goodman graduated from the University of Maryland School of Pharmacy in 1945. He then worked for Read's Drug Stores for over 10 years. In 1958, thanks to a heavy snow storm, Irv had the chance of buying Schmitt's Rexall Drug Store in Westminster, MD. To make a long story short, it was only because of the storm that Irv found out about the store for sale, from a stranger who needed a ride home on that bitter night. When Irv moved out to Main Street, Westminster, there were three other pharmacies within two blocks of Schmitt's Drug Store. Now all the others have ceased operations. His store is known all over the world for his 5¢ Cokes. A few years ago, Channel 11 television did a report on his store and the Coke bargain. Later, a reporter from APS came in for an interview, put it on the APS wire and it was reported in newspapers all over the USA and also in Rome, Italy and Panama City.

Even though, Irv puts in 65 hours a week at his drug store, he has found the time to be an active member of the Carroll County Community. He joined the Kiwanis Club of Westminster in 1958, worked on many programs, and in 1968, became president of the group. There is a Kiwanan Committee called "Operation Drug Alert" in which Irv has been especially interested. Through this committee, he became a member of the



Carroll County Task Force for Youth. Dr. Goodman is now or has been on the Board of Directors of the following organizations: Carroll County General Hospital, Carroll County YMCA, and Carroll County Heart Association. He has also been active with the Mayor's Executive Committee on the Revitalization of Down-Town Westminster, the Heart Association of Maryland, Carroll County Heart Fund, American Red Cross of Carroll County, etc. I can continue with many more of his contributions, but I am sure you already have a good idea of all the fine qualities that Irv possesses.

In 1971, the Lions Club of Westminster awarded the "Humanitarian Man of the Year" award to Irvin Goodman. Then he was entered into a District Award and again he came in first. In 1974, the Board of Trustees, Faculty, and Administration of Western Maryland College gave the "Community Service Award" to him.

Irv and his lovely wife, Hilda, will be married 40 years on June 24, 1985. They have two children, Jeffrey and Linda, both graduates of the University of Maryland with degrees in social work.



PHARMACISTS IN THE NEWS

Above, to the left, is a picture of John F. Fader, II, P.D., as he appeared in his University of Maryland Pharmacy Yearbook of 1963. Take note of his many activities. Today, John is still a very active person. At different times, he has been a pharmacist, attorney, judge, instructor in pharmacy law, etc. It just proves that a good man can wear many hats in his life. At the top right, John is seen recently with a group of lay persons who were selected by Towson Catholic High School to assist in making policies and long range plans for the school. In the picture, he is standing on the left. John's wife, Kathryn, is also a pharmacist and she is working for Caton Pharmacy, 3446 Wilkens Avenue, Baltimore, MD. Kathy graduated from Idaho State University in 1970.

GET WELL WISHES TO:

Angelo C. Voxakis, P.D., UofMD Pharmacy 1971, who recently underwent surgery at St. Agnes Hospital, Baltimore, MD. Dr. Voxakis, who works for the pharmacy at University Hospital, is a past president of the University of Maryland Pharmacy Alumni Association.

LOVE AND MARRIAGE:

Beth Marcy Cohen, P.D., will marry Steven Geller in May 1985. A graduate of UofMD Pharmacy 1982, Beth is working for a community pharmacy. Before pharmacy school, she had graduated cum laude with a B.S. degree in Biology from Loyola College.

Karen Beth Demsky, P.D., will marry Edwin Mi-



chael Lewis, P.D., in June 1985. A graduate of UofMD Pharmacy 1976, Karen is working for the University Hospital Pharmacy and in May 1985, she will become the first female president of the University of Maryland Pharmacy Alumni Association. Mr. Lewis received his B.S. degree in Pharmacy from the Massachusetts College of Pharmacy and his M.S. degree in Institutional Pharmacy from the University of Maryland.

Lee David Pearlman, P.D., will marry Cheryl Lynn Weiner in June 1985. A graduate of UofMD Pharmacy 1978, Lee is presently a senior student at the Ohio College of Podiatric Medicine, Cleveland, OH. He is due to receive his doctorate in podiatric medicine in May 1985.

CONGRATULATIONS TO:

Fred Abramson, UofMD Pharmacy 1956 who sold excess of \$2 million in real estate sales. This information obtained from the March/April 1985 edition of Magill Yerman and Company, Realtors and Better Homes and Gardens.

M. Neal Jacobs, UofMD Pharmacy 1963, who is the publisher of the Bowie Times, an independent community newspaper which is published monthly in Bowie, MD. Neal, the pharmacist-owner of Belair Professional Pharmacy, also writes a very interesting article for this paper called "A Pharmcist's View". Dr. Jacobs is the son of Eugene Jacobs, UofMD Pharmacy 1939. Gene used to own Jefferson Pharmacy in East Baltimore and he has also worked for Sav-A-Lot Drugs.

James W. Polek, UofMD Pharmacy 1980, who is now working for the Pharmaceutical Chemistry section of the Maryland State Department of Health and Mental Hygiene. Jim and his wife, Barbara, have a girl, Meghan, and are expecting another child in June 1985. He formerly worked for Paradise Pharmacy.

What Pharmacists Should Know About the Asthma-Aspirin Sensitivity Link

More than 9 million Americans suffer from asthma. Although the condition is not curable, it is treatable. The best treatment is intervention. For example, pharmacists and physicians can help patients reduce the number and severity of asthma attacks by advising them to avoid aspirin and related drugs that may trigger asthma episodes.

Respiratory specialists estimate that as few as 5 to 10 percent or as many as 39 percent of asthmatics are susceptible to aspirin-induced bronchospasms and they advise that all asthmatics should be careful in their use of this common household analgesic.

Health care professionals have gained little practical insight into asthma through classifying it according to symptoms (such as coughing and breathlessness) or associated clinical conditions (such as allergic rhinitis, eczema or bronchitis) or the periodicity of attacks—(seasonal, perennial, episodic or nocturnal).

However, Dr. E. R. McFadden Jr., director of research, Shipley Institute of Medicine in Boston, stated at a medical roundtable, "Current Clues to the Understanding of Aspirin-Sensitive Asthma," that one group of asthmatics clearly has different pathogenic sequences and perhaps different prognoses: those with aspirin sensitivity.

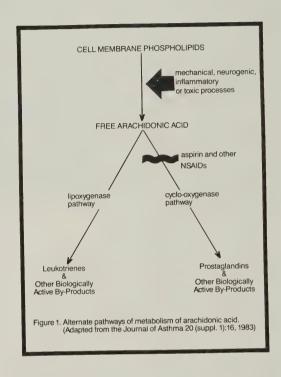
Aspirin-Sensitive Asthmatics

In a recent symposium, "Managing Medication in An Older Population: Physician, Pharmacist, and Patient Perspectives," Dr. Irwin Ziment, UCLA School of Medicine, warned that a person who has asthma or is a candidate for it must be made aware of the potential problem with aspirin.

"If a person also has nasal problems, such as sinusitis, and particularly if he has polyps, there is a very high risk in that situation of aspirin provoking asthma," Dr. Ziment says. "He would be well advised to avoid totally any contact with aspirin."

Mechanism of Sensitivity

Aspirin-induced asthma is not due to an allergic reaction involving the immune system. Rather, aspirin interferes with the metabolism of arachidonic acid, a structural component of cell-membrane phospholipids. This result in an imbalance of by-products, some of



which are responsible for the bronchospastic reaction.

Arachidonic acid is metabolized either by way of the cyclooxygenase or lipoxygenase pathway (see diagram). The cyclooxygenase pathway yields an important series of compounds, the prostaglandins (PGs). These help regulate vascular and airway smooth muscle tone.

The lipoxygenase pathway yields a different series of products. These have a major role in the inflammatory process. Some of the metabolites, the leukotrienes, have bronchospastic activity and appear to be responsible for many of the clinical and pathological manifestations of bronchial asthma, including bronchoconstriction and excess mucus production.

Aspirin inhibits an enzyme in the cyclo-oxygenase system and shifts the equilibrium of arachidonic acid breakdown towards the lipoxygenase pathway (see diagram). The increased leukotriene production may result in an acute, perhaps life-threatening, asthma episode for the aspirin-sensitive asthmatic.

Other Analgesics

Many other analgesics are absolutely contraindicated in patients with aspirin-induced asthma. Nonster-

oidal anti-inflammatory drugs (NSAIDs) such as indomethacin (Indocin®) mefenamic acid (Ponstel®), flufenamic and meclofenamic acids (Meclomen®), ibuprofen (Motrin®, Rufen®), fenoprofen (Nalfon®), naproxen (Naprosyn®) and phenylbutazone (Azolid®, Butazolidin®) can precipate bronchoconstriction and lead to life-threatening attacks. For the same reason, several that are not currently available in this country—ketoprofen, diclofenac, amidopyrine, noramidopyrine, fenflumizole and ditazole—should be avoided.

Acetaminophen (Tylenol®) lacks anticyclo-oxygenase activity and can usually be used as an alternative analgesic. In a clinical trial conducted by Dr. Constantine Falliers at the Allergy and Asthma Clinic, Pediatric Center, in Denver, a positive history of aspirin intolerance was not associated with any detectable risk of acetaminophen intolerance.

Basic Defect Unknown

Asthma, originally defined simply as a state of breathlessness, is now recognized as a distinct disease that can be triggered by a wide variety of factors. Allergic reactions to dust, pollen, animal dander, certain foods and other allergens can precipitate acute episodes of asthma. Exercise, emotional stress, low temperature and decreased moisture content of inhaled air may also be causative factors.

The basic defect that causes asthma is unknown, as is the relative importance of each of the above factors in triggering the disease. Researchers speculate that perhaps the basic mechanism behind aspirin sensitivity may be a clue to a better understanding of asthma.

Many asthma patients are not aware of how many over-the-counter products contain "hidden" aspirin or related medications. The pharmacist can take the initiative in educating asthma patients as to the importance of reading and understanding labels, reinforcing the pharmacist as a vital member of the health care team.

This article is based on the proceedings of the symposium, "Current Clues to the Understanding of Aspirin-Sensitive Asthma" sponsored by McNeil Consumer Products Company, and published as a supplement to the JOURNAL OF ASTHMA, 1983

For further information or a copy of the complete symposium, write to McNeil CPC, Camp Hill Road, Ft. Washington, PA, 19034; ATT: COMMUNICATIONS DEPARTMENT





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Nurse Prescribing



Health Spending Cuts



Nonprescription
Drug Trends



New Drug Rules



An American Nurses' Association survey shows that 18 states have passed legislation or rules granting prescription writing authority to nurses. The regulating body for the prescribing function is the board of nursing in 14 states, and the board of medicine in the other four. Drugs which may be prescribed are limited by state formulary in four states, and no limits are specified by two states. Controlled substances may not be prescribed in three states, and only certain classes of control-

led substances may be prescribed in four. To prescribe drugs, an arrangement with a collaborating physician is required by five states, an arrangement with a supervising physician is required by six states, and a written agreement with a physician is required by six states. The survey also found that physician assistants have been granted prescribing privileges in 12 states, while pharmacists are authorized to prescribe in two states.

Health spending is one of the Reagan Administration's major targets as it tries to slash Federal budget deficits. Health cuts, in fact, comprise a full 10% of the spending reductions the Administration is seeking this year. Special attention is being paid to slowing the growth of the Medicaid program, as the Administration looks to replace the present system of open-ended Federal payments to states with strict restraints on spending. In addition, future Federal spending

increases would be limited to inflationary adjustments tied to the Medical Care Component of the Consumer Price Index. The net result, says the Administration, is that "states would have an incentive to adopt further cost-containment measures." It is reasonable to expect that the prescription drug component of the state Medicaid programs will be among the services scrutinized as the states look for ways to cut costs.

What are the trends that will affect your nonprescription drug department in the years ahead? Latest statistics show that by 1990, the "baby-boomers" (aged 26-44) will be the single largest age group in the country—comprising about a third of the population, or 82 million people. They will also control about 51% of the nation's total spending power. This group has a growing interest in the

concept of wellness—which translates into more purchases of vitamins, personal grooming products, and health care remedies. The other large segment by 1990 will be those 55 and older—they will make up 21% of the population. This means stronger demands for product categories such as analgesics and antacids.

The Federal government will be instituting new rules designed to dramatically speed its review of new drugs and upgrade drug safety monitoring. The new procedures, termed the most important change in FDA regulations in more than 20 years, are designed to cut as much as six months from the two or more years now required for new drug approval. According to FDA, a speed-up of just two

months for 15 therapeutically significant drugs per year would benefit more than 200,000 Americans. In addition, the regulations add a new "safety update report" while FDA has a New Drug Application under consideration to ensure that reviewers are provided the most current safety-related information while a drug is in the approval process.



MPhA Introduces A New Member Service and Journal Feature

The patient education aid on the right is the second in a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, Md. 21201.

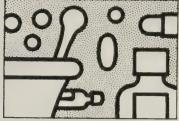
The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other information, place such information so that it covers the artwork in the upper right hand corner.

See the article on page 20 of this issue for additional information related to this patient education aid.



Things You Should Know FOR YOUR GOOD HEALTH



Parents Should Be Very Cautious About Giving Aspirin to Ill Child

The season for Reye syndrome has begun, and parents should be extremely cautious about giving aspirin to children who are suffering from influenza (flu) or chickenpox. Cases of Reye syndrome occur at all times of the year, but they tend to cluster during flu season, and during late winter and early spring, the typical season for chickenpox.

Reye syndrome is an acute condition that may occur anywhere from two days to two weeks after a child has recovered from influenza or chickenpox infections. It is not a disease but a "syndrome," meaning a combination of signs and symptoms.

Children from infancy to their late teens can be affected. It is characterized by sudden and persistent vomiting, violent headaches and unusual behavior in children who appear to be recovering from an often mild viral illness. It requires immediate diagnosis and admission to a hospital where emergency care can be provided. Reye syndrome is uncommon, but when it does occur it is considered life-threatening.

The syndrome is an abnormal accumulation of fat in the liver and other organs, accompanied by severe swelling of the brain with an increase in pressure in the brain. Although it affects all organs, the most serious effects are in the liver and the brain.

Reye syndrome is not new. In 1925 it was considered a form of meningitis, an "inflammation of the brain area." In later years it was

more accurately described as edema (swelling) of the brain.

Although the cause of Reye syndrome is not known at this time, recent studies indicate there may be a relationship between the occurrence of the syndrome and taking aspirin, or medication that contains aspirin, during the chickenpox or influenza that preceded it.

The Food and Drug Administration has proposed that aspirin and other salicylates, and medications containing aspirin, be labeled with a warning against giving them to children under the age of 16 with influenza, chickenpox or other flulike illnesses. Aspirin does not necessarily cause Reye syndrome, but it may make some children more susceptible to the development of the syndrome.

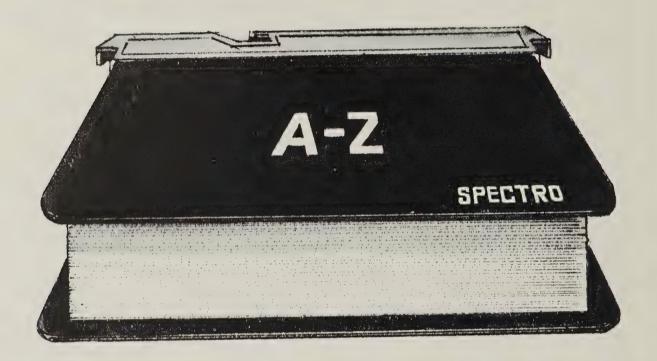
Salicylates are compounds used in medicines to lessen pain, reduce fever or cut down on inflammation. Products containing salicylates are also used in external analgesics, such as body rubs.

Childhood illnesses are usually minor and self-limiting, meaning that they will go away without treatment. In most cases, it is unwise to give aspirin to a child with a viral illness, and it is also unnecessary. There are times, however, when aspirin and other salicylates should be used. For example, aspirin is often the recommended medication for rheumatic fever and rheumatoid arthritis. It is also recommended for simple pain.

Always consult with your pharmacist or physician before giving your children any medication.

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The management of both ethylene glycol and methanol poisoning present the clinician with a unique management situation. The central nervous system and nephrotoxicity associated with ethylene glycol and the ocular toxicity of methanol are toxic manifestations of their metabolites. In addition to supportive care, GI decontamination and correction of metabolic complications, antidotal therapy with ethanol should be instituted in patients presenting with a history of ethylene glycol or methanol ingestion. Ethanol competes for the enzyme alcohol dehydrogenase at the first step in the metabolism of these alcohols thereby preventing formation of their toxic metabolites. In order to insure saturation of the enzyme and guard against excessive ethanol toxicity, ethanol blood levels should be maintained within the range of 100-200 mg/dl. A method for initiating and maintaining adequate ethanol levels is described below.

Ethanol obeys Michaelis-Menten, (dose dependent) kinetics.² The usual loading dose (LD) of ethanol is 0.6 g/kg. This is derived using the following pharmacokinetic relationship:

$$LD = Cpo \times Vd$$
 (Eq. 1)

where Cpo (100 mg/dl) is the desired initial plasma concentration and Vd (0.6 L/kg) is the estimated volume of distribution of ethanol in adults.³

The initial maintenance dose of ethanol is 110 mg/kg/hr. This dose is derived by using the following Michaelis-Menten relationship:³

$$Ko = \frac{(Vm) (Cpss)}{Km + Cpss}$$
 (Eq. 2)

where Ko (mg/kg/hr) is the administration rate, Vm is the theoretical maximum rate of elimination of ethanol (75 mg/kg/hr for non-drinkers to 175 mg/kg/hr in chronic drinkers; average Vm = 125 mg/kg/hr), Km is the plasma concentration at which the metabolic rate is one half of the maximum rate (138 mg/L) and Cpss (100 mg/ll) is the desired steady state plasma concentration.⁴

Since neither ethylene glycol nor methanol are very effectively eliminated by the kidneys, hemodialysis in addition to ethanol therapy is necessary to remove these compounds and their metabolites in severe overdosage. During hemodialysis an additional 7.2 g/hr of ethanol hould be admimistered to account for that lost to dilysis.⁴

Information contributed by the Maryland Society of Hospital Pharmacists.

Contributor: Gregory P. Wedin
Fellow in Toxicology
Maryland Poison Center

To convert mgs. of ethanol into mls. of a particular concentration of ethanol the following relationship can be used (Density of 100% ethanol = 790 mg/ml):

$$\frac{\text{mls. of }}{\text{Ethanol}} = \frac{\text{Desired mgs. of Ethanol}}{\text{Density}} \times \frac{\text{Concentration of ethanol } (\% \text{ v/v})}{100}$$

For example, the loading dose of ethanol in a 70 kg patient would be 42 grams (0.6 g/kg). If 80 proof (40% v/v) ethanol were used, the dose would be 133 mls.

The concentration of ethanol solution which should be administered to the patient is dependent upon the route of administration. If administered orally, the concentration of ethanol should not exceed 30%-50%. High concentrations of ethanol can cause gastritis and can also decrease GI emptying which in turn will decrease the rate of ethanol absorption. If administered intravenously, concentrations should not exceed 5-10% to avoid phlebitis⁵ and either D5W or NS can be used as a diluent. The oral route is usually preferred because of ease of administration and potential problems with large fluid volumes which may need to be administered intravenously. If given by intravenous infusion, the loading dose is infused over 30 minutes followed immediately by the maintenance infusion. If given orally, the loading dose is given within 30 minutes followed by hourly maintenance doses beginning one hour after the loading dose was initiated. Therapy is continued until either ethylene glycol or methanol is removed from the body.

The above recommendations provide only a starting point. The wide interindividual difference in rates of ethanol metabolism and differences in dialysis clearance, requires hourly monitoring of blood ethanol levels when initiating therapy or dialysis. Once ethanol levels are stabilized, every four hour monitoring should suffice.

In summary, using this organized approach will help to insure safety and efficacy of enzyme inhibition, maximize efficacy of therapy and minimize toxicity of the ingested substances.

If you have any questions about this or other poisonings, please do not hesitate to call the Maryland Poison Center 528-7701 or 1-800-492-2414.

REFERENCES

- 1. NEJM 1981; 304:21-23.
- 2. J Pharm Sci 1976; 65:152-4.
- 3. Management of the Poisoned Patient 1977: 103-14.
- 4. Am J Med 1979; 67:804-807.
- 5. AJHP 1981; 38:1024-27.

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Ronald Sanford, President of the MPhA, was recently promoted to the newly created position of Vice President of Pharmacy Administration for Dart Drug Stores. Dart is engaged in the operation of over 80 retail pharmacies in the Washington, Baltimore and Richmond areas.



Kimberly S. Giesen has been assigned to the Charles County Territory for the Upjohn Company. She is a graduate of Hood College.



Roche Labs is offering a pharmacy catalog which describes a wide range of accredited continuing education programs for both independent and group study. To receive a free copy of the catalog, contact Roche representatives or write to their Department of Pharmacy Affairs.



A group of Health Care Lobbyists relax after midnight on the final night of the 1985 Maryland General Assembly session. (They deserve to relax, it was a tough session). For a report on some of the bills which affect Pharmacy, check out the "Legislative Wrapup" on page 4 of this issue!

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

DUODENAL ULCERS:

Patients with duodenal ulcers were given various doses of cimetidine (Tagamet) and the incidence of recurrent ulcer formation was studied for one year. Patients at greatest risk were smokers, so the authors have concluded that since smokers receiving cimetidine were at least as likely to have a recurrence as were non-smokers taking a placebo, cessation of smoking may be more important than drug therapy in preventing recurrence of duodenal ulcers. N Engl J Med, Vol. 311, #11, p. 689, 1984.

ANTINAUSEANT EFFECTS:

The antineoplastic agent cisplatin (Platinol) is one of the most nauseating substances used in modern medicine. Vomiting and extreme discomfort is common and is often refractory to standard antinauseant regimens. Investigators have found that dexamethasone (Decadron) in combination with metoclopramide (Reglan) protects two-thirds of the patients receiving cisplatin therapy. Recent reports have also found dexamethasone useful as an antinauseant in situations where the nausea was caused by less powerful agents. *Br Med J*, Vol. 289, #6449, p. 879, 1984.

SMOKING:

Men with cardiovascular problems were studied to determine what effect smoking might have on myocardial infarctions, cardiomyopathies, and coronary stenosis. Statistical analysis of the data suggests that although smoking does predispose one to risk of cardiomyopathies and transmural myocardial infarction, it does not increase the risk of coronary stenosis. *N Engl J Med*, Vol. 311, #19, p. 1201, 1984.

CYSTIC FIBROSIS:

Cystic fibrosis is a condition hypothesized to be due to a genetic defect. It is the most serious genetic disease in Caucasians. Patients secrete thick mucous which is difficult to clear from the airway. The composition of perspiration is abnormal and deficiencies in pancreatic enzyme activity is noted. It is apparent that most of the symptoms of cystic fibrosis are due to the inability of the chloride ion to permeate the membrane of specialized epithelial cells. Investigators are trying to identify drugs which may be able to help facilitate chloride transport in these tissues. *JAMA*, Vol. 252, #18, p. 2519, 1984.

MORPHINE TOLERANCE AND DEPENDENCE:

Several opiate receptors have been identified and roles for each receptor subtype are being sought. In-

vestigators have evidence to suggest that the development of tolerance and dependence characteristic to opiate use is achieved via activation of a subtype of mu receptor in the cord and in the central nervous system. *J Pharmacol Exp Ther*, #1, p. 91, 1984.

ILOPROST:

Prostacyclin (PGI₂) is a potent vasodilator with antiplatelet activity. Its biological half-life is so short that it does not lend itself well to exogenous administration. An analog of prostacyclin, iloprost, produces the same activity as does prostacyclin, but has a longer plasma half-life. Initial reports suggest that iloprost may be useful in treating patients with advanced obliterative peripheral arteriosclerosis, Raynaud's phenomenon and in extracorporal circulation procedures such as hemodialysis and cardiopulmonary bypass. *Clin Pharmacol Ther*, Vol. 36, #4, p. 464, 1984.

NEW DRUGS:

Several new drugs will appear for general use within the near future. Ceftazidime (Fortaz) is a cephalosporin which is said to have good activity against *Pseudomonas* organisms. Monolactam antibiotics should also start to appear before too long. A narcotic antagonist, naltrexone (Trexan), is said to be ready for general use as is the oral form of nalbuphine (Nubain). A throat gargle containing benzydamine (Tantum) is also pending approval by the FDA. Pirbuterol (Exirel) is a beta-2 agonist and levonorgestrel is a progestational agent which may appear in new oral contraceptive formulations. Fenoterol (Berotic) is also nearing approval. (Editor.)

ABDOMINAL TRAUMA:

Patients experiencing penetrating abdominal trauma were treated with either cefoxitin (Mefoxin) or a combination of clindamycin (Cleocin) and gentamicin (Garamycin). Both regimens were found to be comparable with respect to effectiveness, toxicity and cost of therapy. *N Engl J Med*, Vol. 311, #7, p. 1065, 1984.

METRONIDAZOLE-WARFARIN INTERACTION:

Metronidazole (Flagyl) potentiates the effects o warfarin (Coumadin) probably via several differen mechanisms. The anti-infective agent not only inhibit the metabolism of the anticoagulant, but apparently i capable of displacing it from plasma protein thus in creasing the concentration of free warfarin in th plasma. Additionally, metronidazole seems to increas the elimination rate constant for the endogenous protein thus decreasing the activity of th normal clotting mechanism. *J Pharmacol Exp Thei* Vol. 231, #1, p. 72, 1984.

AMIFLAMINE:

The monoamine oxidase inhibitors have been used in limited amounts because of their propensity to cause hypertensive reactions when food or drugs containing tyramine or other indirect-acting adrenergic agents are administered. Since two different forms of monoamine oxidase enzymes with different substrates and inhibitor specificities have been identified, efforts to develop a specific inhibitor of MAO-A have been increased. Results of this investigation have produced amiflamine, a specific inhibitor of monoamine oxidase-A. This does not interact with tyramine and thus may lead to a reduction in side-effects associated with monoamine oxidase inhibitor administration and increase the usefulness of this group of drugs. *Clin Pharmacol Ther*, Vol. 36, #3, p. 515, 1984.

RESPIRATORY TISSUE RESPONSES TO ANTIHISTAMINES:

Histamine has been shown to cause bronchiolar constriction and an increase in the permeability of the respiratory tissue to a low molecular weight radio-isotope. When the standard histamine-1 antagonists were administered prior to the histamine challenge, the bronchiolar constriction was prevented but no effect was seen on tissue permeability. Ranitidine (Zantac) was used as a pretreatment and the histamine challenge repeated. This time there was no effect on bronchiolar muscle tone but the histamine-induced increase in respiratory tissue permeability was decreased. It is postulated that the histamine-2 antagonists may play a clinically important role in the prevention of asthmatic attacks via the prevention of increased tissue permeability. *Lancet*, Vol. 8399, #11, p. 372, 1984.

KETANSERIN:

Intermittent claudication is a condition which is generally resistant to most commonly used drugs including isoxsuprine, nylidrin, etc. Pentoxifylline (Trental) has produced beneficial activity so a search continues for other effective agents. Ketanserin, a selective serotonin antagonist of the 5HT-2 receptors, has been found to be useful when used chronically in patients with intermittent claudication. The 5HT-2 receptors are found on vessel tissue and on platelets and apparently participate in the regulation of circulation. *Lancet*, Vol. II, #8406, p. 775, 1984.

WARFARIN-CHLORAMPHENICOL INTERACTIONS:

Chloramphenicol administration has been shown to increase the potency of warfarin (Coumadin) as reflected by an increase in the prothrombin time reading. Although the activity of the anticoagulant can be ennanced via several different mechanisms, it seems clear hat non-stereospecific inhibition of warfarin metabolism is the only factor altered in the presence of the antibiotic. *J Pharmacol Exp Ther*, Vol. 231, #1, p. 80, 1984.

CUSHINGS DISEASE:

Cushings disease associated with excessive pituitary activity is responsible for most conditions of endogenous hypercortisolism. Surgical correction is associated with risk and expense, so alternate methods of therapy have been sought. Investigators in Great Britain have been successful in treating this condition with low dose, external pituitary irradiation. Some patients experience complete remission within 6 to 12 months and have remained free for up to 8 years. *Br Med J*, Vol. 289, #6446, p. 643, 1984.

AMINOGLUTETHIMIDE:

Patients using high doses of aminoglutethimide and hydrocortisone were found to experience a drastic reduction in the adrenal synthesis of steroids (medical adrenalectomy) but side-effects of lethargy, ataxia and rash caused the drugs to be discontinued in up to 10% of those on therapy. When used in these doses, aminoglutethimide was found to inhibit the action of the desmolase enzyme system which converts cholesterol to pregnenolone. At lower, more tolerated doses of aminoglutethimide, the drug was found to inhibit the aromatic enzyme system which converts androgens to estrogens in peripheral tissue. This has application in treating women with advanced breast cancer because it not only reduces estrogen concentrations without producing adrenal suppression, but the low dose lacks many of the side-effects associated with the higher dosage regimens. Lancet, Vol. II, #8403, p. 604, 1984.

DEBRIDING ENZYMES:

Debridement is a necessary part of management of contaminated wounds. Surgical debridement is useful but not always appropriate. The clinician should be familiar with non-surgical methods of debridement. The traditional methods, i.e., wet-to-dry, Dakins Solution and mechanical cleansing are useful when only small amounts of debridement are necessary. Methods such as the occlusive or semi-occlusive dressings cause debridement via the patient's own white blood cell activity, but pose a risk of infection. Proteolytic enzymes can be used in lieu of surgery or in conjunction with surgery to remove larger amounts of necrotic tissue. Though some studies question the effectiveness of the enzymatic preparations, they have been found beneficial when used properly. Enzymes perform best in a moist environment. Some products, such as Travase or Santyl Ointments, are less effective is used with detergents which contain heavy metals or when used in acidic environments. If the debriding enzyme is used in an approved manner, it will be effective in removal of large amounts of necrotic tissue when surgical debridement is not available or when occlusive dressings or gauze pads are not feasible. J Enterostomal Ther, Vol. 11, #3, p. 122, 1984.

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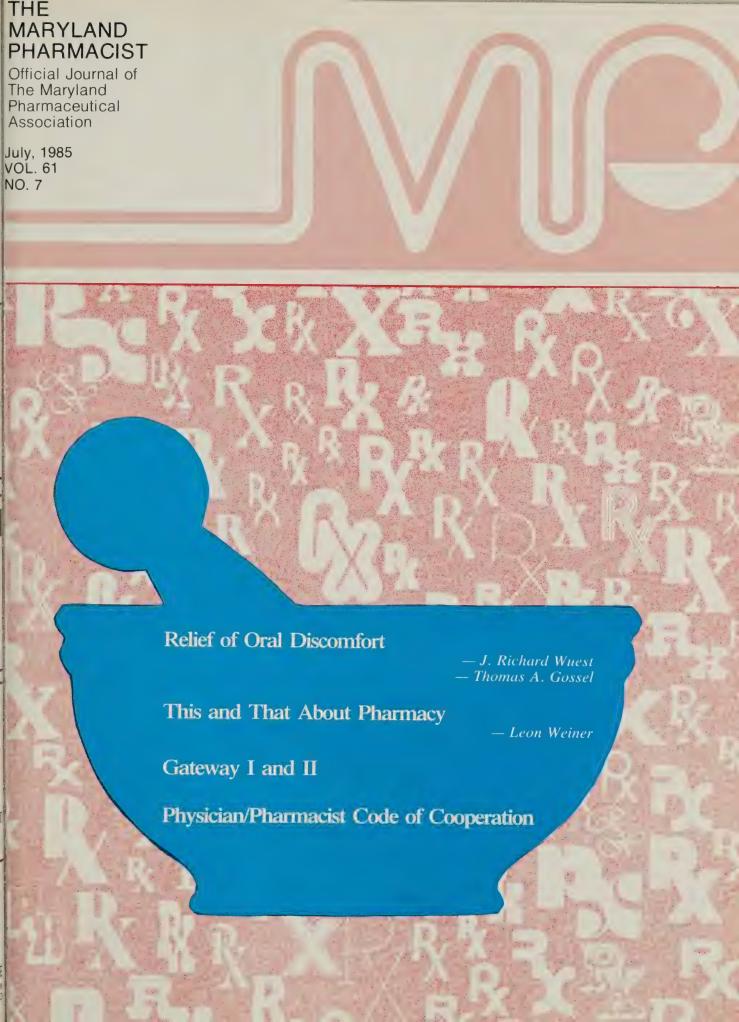
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It seems like just yesterday that I assumed the Presidency of the Association. Now, just one day later, I am turning over the reins to a most capable leader. This year was one of the fastest moving of my professional career. It would seem that almost every President's Message was due yesterday because the journal had already gone to press, and each meeting seemed to run into the next one. With this hectic schedule, there were many major issues faced by pharmacy and the Association this year, not the least of which was the passage of mandatory continuing education as a result of a resolution at last year's convention. Of particular concern to the Association this year was the success in freedom of choice with HMO's in the state and the beginnings of a pharmacist Buying Group. Of significant concern to the Association this year was the loss of the generic incentive in the Medicaid program (we're still working on it!).

My year as your President has been very rewarding, my only regret is that it seemed to pass so quickly. Having served on the Board of Trustees and various committees within the Association never game me the full appreciation of our Executive Director as I have gained during my year as "Captain of the Ship." We have a truly remarkable and dedicated gentleman running the Association office and keeping all the ends tucked in (and the dirt under the rug?). My thanks to Dave for his tolerance of my continual lateness of the President's Messages and even this final one! My thanks also to the Officers, Board Members, Committee Chairmen and Committee Members who gave so freely of their time and talents in making this year the success that it has been. My thanks to Sam Lichter, whose conversation in the lobby of the Carousel Hotel inspired me to run for Presidency; my thanks to my good friend Mel Rubin and his guidance and help and unflagging loyalty to the Association. I believe he secretly is on every Committee! Finally, my thanks to my wife Betty, who gave freely of her husband to attend the various meetings (especially four days at APhA in San Antonio) and her tolerance of missed dinners and late night meetings.

I started out last year introducing you to the Officers and Board of Trustees, pointing out the variety of practice settings represented. I have personally and professionally benefited from my association with your elected representatives, I hope you have felt the same benefit. Having been the first Chain representative to have aspired and achieved the Presidency gives me a feeling of great pride and accomplishment. It didn't hurt too bad did it? I am sure there were many who were very concerned that the control of the Association was shifting to the dreaded chains. Our incoming President faces similar problems (some describe problems as opportunities) in that she is a woman—the first woman President of the Association. Being dually from community practice and academia, she represents multiple facets of the profession in one person or is she really only one person since she has the energies of a small army. I extend my sincere hope to Madeline Feinberg for a most successful year.

Delivered at the 1985 annual convention.

Ronald A. Sanford, P.D.

PRESIDENT 1984-85.

SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 5

Advising Consumers on OTC Products for Relief of Oral Discomfort

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Goals

The goals of this lesson are to:

- 1. define terms relating to oral health care:
- describe the treatment of minor mouth disorders with OTC agents.

in the rervice

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Objectives

At the completion of this lesson, the successful participant will be able to:

- 1. recognize safe and effective OTC agents for treating minor mouth disorders;
- 2. identify the pharmacologic action of OTC oral and dental products:
- 3. explain the proper technique for applying these products;
- 4. know when to refer the patient to a dentist or physician.

Glossary of Oral Health Care Terms

- Abrasion: the wearing away of tooth substance through some mechanical process; usually occurs on the exposed root surfaces of teeth, but may be seen elsewhere.
- 2. Abrasive: a solid material which cleans or polishes. Abrasives are important inactive ingredients in anticaries dentifrice formulations, and typically comprise up to 50 percent of the total formulation. Abrasives are added to dentifrices to facilitate mechanical removal of dental plaque, debris, and stain from tooth surfaces.
- 3. Anesthetic: a drug which causes reversible loss of feeling or sensation. General anesthetics are given by inhalation or intravenous injection, and they cause a loss of consciousness as well as a loss of sensation. Local anesthetics are applied directly to the nerve tissue in which they block sensory receptors and passage of nerve impulses centrally.
- 4. Anticaries Agent: an agent which aids in the prevention of dental caries (decay or cavities).

Antimicrobial Agent: an agent that kills microorganisms, or prevents or inhibits their growth and reproduction, and contributes to claimed effects of the product in which it is included. An antimicrobial preservative is an agent that kills organisms, or prevents or inhibits their growth and reproduction. It is included in a product formulation only at a concentration sufficient to prevent spoilage or prevent growth of inadvertently added microorganisms, but does not contribute to the claimed effects of the product to which it is added.

6. Antiseptic: an agent that contains chemicals intended to kill or temporarily prevent multiplication of harmful germs which may be present on the skin or oral mucous membranes.

 Astringent: an agent that causes contraction of the tissues or arrest of secretions by coagulation of proteins on a cell surface.

- 8. Cementum: the bonelike material covering the root of the tooth. Cementum contains 45 to 50 percent organic, and the balance, inorganic matter. It contains many fibers which attach the tooth to the bone.
- 9. Counterirritant Drug: an irritating drug that is applied locally to the skin or oral mucosa for relief of pain originating from a structure other than the site of application. For example, a counterirritant drug might be applied in a dental poultice to the oral mucosa surrounding a tooth with a painful pulp.
- 10. Debriding Agent: an agent which causes the removal of for eign material or devitalized or contaminated tissue from or ad jacent to a traumatic or infected lesion to expose surrounding healthy tissue.
- 11. Decongestant: an agent that re duces congestion or swelling In OTC use for mucous mem branes, the term generally reference.

to sympathomimetic drugs that act by vasoconstriction.

2. **Demulcent:** a bland, inert agent that soothes and relieves irritation of inflammed or abraded surfaces such as mucous membranes.

3. Dental Calculus: mineralized dental plaque that accumulates on the tooth surface principally at the gum margin. One of the major fates of plaque is mineralization. Plaque serves as a matrix for calculus formation. The surface of calculus is usually covered with a nonmineralized

layer of plaque.

4. Dental Fluorosis: a mottling (discoloration) of tooth enamel resulting from imperfect mineralization associated with excessive ingestion of fluoride. Brown or black stains develop because the poorly calcified surface absorbs colored materials. The frequency and extent of dental fluorosis is chiefly related to the fluoride content of drinking water.

5. Dental Gel: a dosage form for delivering an anticaries agent to aid in the prevention of tooth decay; formulated in an anhydrous glycerin base with suitable thickening agents included

to adjust viscosity.

6. Dental (Dentin) Hypersensitivity: a term which implies that the teeth are much more reactive than normal to sensory stimuli such as heat, cold, sour, sweet, or touch. Hypersensitivity can occur when dentin is exposed to the oral environment as a result of gum recession, abrasion, erosion, or a defect in the enamel or cementum.

7. Dental Plaque: a gel-like mat firmly attached to the surface of a tooth or restoration, but removable from exposed areas by thorough mechanical cleansing; the gel-like mat is made up of

the following:

a. Microbial Masses. Microorganisms are the dominant components of mature plaque. The microbial composition of plaque is complex, but in general, an initial predominance of gram-positive organisms

eventually shifts to gramnegative, along with a shift of aerobes to anaerobes.

Intermicrobial Matrix. This is a polysaccharide-protein complex derived from bacteria and saliva, and in areas adjacent to the gingival tissues, from gingival fluid. Of the polysaccharides. dextran and levan are the most significant; both are extracellular polysaccharides produced by bacteria. Dextran is the more significant because of its greater quantity and relative insolubility; levan is a much smaller component of the matrix and is used as a carbohydrate nutrient by plaque bacteria in the absence of exogenous sources.

Nonbacterial Cellular Inclusions. Both the epithelial cells derived from the tissue in the crevices between teeth and the leukocytes migrating across that area contribute to plaque forma-

tion and structure.

18. **Dental Rinse:** a term used to designate a liquid dosage form for rinsing between and around the teeth.

- 19. Dental Tubules: microscopic channels in the dentin which contain: (a) the odontoblastic process (projection of the dentin-producing cells which line the pulp chamber and produce dentin); (b) tissue fluid bathing the process; and (c) varying degrees of mineral. While it is controversial whether these tubules contain nerves, there is general agreement that the tubules contain the means for transmitting pain perception.
- 20. **Dentifrice:** a substance used with a toothbrush to clean the accessible surfaces of the teeth. Dentifrices are ordinarily composed of water, detergent, humectant, binder, flavoring agent, and finely powdered abrasive as the principal ingredients.
- 21. **Dentin:** the calcified tissue forming the bulk of the tooth. It is composed of approximately 70 percent inorganic material, 18 percent organic material, and

12 percent water. Dentin is covered by the enamel of the tooth crown and the cementum of the root. It encloses the soft pupal tissues of the tooth. Dentin is a tubular structure, and processes from cells in the pulp (odontoblasts) penetrate the dentinal tubules. There are three types of dentin: see primary dentin, secondary dentin, and tertiary dentin.

- 22. **Dentin Densensitizer:** a drug which acts on the dentin to block perception of stimuli perceived by patients with dental hypersensitivity. This term is synonymous with tooth desensitizer.
- 23. **Dental Poultice:** a topical dosage form which is confined within a porous sac and is applied to the oral mucous membrane in order to supply medication in the presence of heat and moisture.

24. **Detergent:** surface-active ingredients which facilitate the removal of foreign matter from solid surfaces when they are washed.

- 25. Enamel: the compact and hard substance that covers the crown of the tooth and provides protection for the dentin. The inorganic content of mature enamel is 96-97 percent, the remainder consisting of organic matter and water.
- 26. Fluoride: the negatively-charged atom of the chemical element fluorine. The deposition of fluoride in dental enamel has been shown to increase resistance to enamel solubility and, therefore, dental decay.

27. Gargle: a fluid, which may be flavored, medicated, or both, used to rinse or bathe the posterior part of the oral cavity, with the additional intent to expel mucus from the throat.

28. **Germicide:** an agent that destroys microorganisms. The term includes bactericide, fungicide, virucide, and amebicide.

29. **Gingivitis:** inflammation occurring in the gums as a response to bacterial plaque.

30. **Iodophor:** there are at least three categories of iodophors: (1) hydroalcoholic solutions of elemental iodine and iodides; (2)

elemental iodine complexed with various surfactant compounds; and (3) elemental iodine complexed with various nonsurfactant compounds such as PVP-iodine complex

(povidone-iodine).

31. Mouth Odor: a general term for an odor emanating from the oral cavity. It may or may not be offensive. When such odor is perceived as unpleasant, obnoxious, offensive, or objectionable, terms such as malodor, halitosis, or bad breath may be used.

- 32. Mouth (Oral) Rinse: a solution, often containing breath-sweetening, astringent, demulcent, detergent, or germicidal agents, which is used for refreshing and cleansing the mouth, or for gargling. In some instances, such a vehicle may be used to deliver an active drug to the oral mucosa or teeth. A dental rinse is a liquid used to rinse between and around the teeth.
- 33. **Necrosis:** refers to circumscribed localized areas of cell or tissue death caused by almost any type of severe injury.
- 34. Oral Mucosal Analgesic: an ingredient used in dental care drug products for topical application in the oral cavity to provide temporary relief of oral discomfort by an anesthetic or analgesic effect.

35. Oral Mucosal Injury Agent: an agent which relieves oral soft tissue injury, by cleansing or promoting the healing of oral wounds (minor oral irritations).

- 36. Oral Mucosal Protectant: an agent which is a pharmacologically inert substance that forms an adherent, continuous, flexible, or semirigid coating when applied to the oral mucous membranes. This coating protects the area from further irritation due to the activity of oral structures.
- 37. Pellicle: a product of saliva which is bacteria-free and contains glycoproteins, derivatives of glycoproteins, polypeptides, and lipids. A cleaned tooth surface will form a pellicle within minutes. The formation of this structure is believed to be the first step in plaque formation,

although not always a necessary prerequisite.

38. Pharynx (Throat): the musculomembranous sac between the mouth and nostrils and the esophagus. It is continuous below with the esophagus; above it connects with the mouth, nasal passages, and auditory (Eustachian) tubes. It is subdivided into the following parts:

(a) Nasopharynx: the part above the level of the soft

palate

(b) **Oropharynx:** the part that lies between the soft palate and the upper edge of the epiglottis.

(c) Laryngopharynx: the part that lies between the upper edge of the epiglottis and opens into the larynx and esophagus (sometimes called hypopharynx).

- 39. **Plaque:** a patch on the surface of the oral mucosa or tooth made up of a mass of microorganisms. Depending on bacterial activity and environmental factors, it can give rise to caries (cavities), calculus, or inflammatory changes in the mucosal surface or tooth.
- 40. Primary Dentin: the well-structured dentin that is deposited during the original formation of the tooth. Dentin deposited later in life differs in structure and can be distinguished from primary dentin microscopically by a demarcation line that stains darkly.
- 41. Secondary Dentin: dentin formed after the original primary dentin of the tooth has been deposited. It forms on the inner, or pulpal surface of the primary dentin as a physiologic process or as a pathologic response to thermal, mechanical, or chemical irritants. Secondary dentin is not as well-structured as primary dentin and can be distinguished microscopically by its irregular morphologic pattern.
- 42. **Sloughing:** a slough is a mass of dead tissue in, or cast out from, living tissue. Sloughing is the formation or separation of dead from living tissue.

43. Tertiary Dentin: designates den tin formed as a result of more se vere injuries or insults to the tooth, such as dental caries marked abrasion, or extensiv erosion. Tertiary dentin is c very poor structure and is limit ed to the area of irritation.

44. Toothache Remedy: an agen used for the temporary relief c pain arising as a result of a:

open tooth cavity.

45. Topical Analgesic: a substanc applied to an epithelial surfac (e.g., skin or mucous membrane that relieves pain without neces sarily abolishing other sense tions; or one that causes partic blockade of subcutaneous c submucosal terminal nerve encings so that a minimal stimulu evokes no painful response, bu a greater stimulus does.

Advising Consumers on OTC Products for Relief of Oral Discomfort

This lesson will review importan aspects of oral and dental care, an the OTC drugs appropriate for sel use in preventing or treating oral di eases and injuries. To assure that th reader understands the common te minology used throughout this le son, attention is directed to the Glo sary of Oral Health Care Terms. Th terminology was derived from the definitions that we ''official'' adopted by various FDA adviso panels which reviewed oral heal care drugs. It is recommended th participants save this glossary for f ture reference.

OTC Agents Used to Relieve Oral Discomfort

These agents fall into five broadless, i.e., oral mucosal analgesics; oral mucosal protectants; 3) too desensitizers; 4) toothache remediand 5) products for oral health cai.e., analgesic/anesthetic antimicrobials, astringents, debring agents, decongestants, demicents, and expectorants. Three of the four categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants a toothache remedies) contain at lesson in the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants a toothache remedies) contain at lesson in the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants a toothache remedies) contain at lesson in the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants at the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants at the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants at the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants at the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants) at the categories of agents that are viewed in this lesson (i.e., mucosanalgesics, mucosal protectants) at the categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson (i.e., mucosanalgesics) are categories of agents that are viewed in this lesson

one ingredient that was ruled to be safe and effective for continued OTC marketing. More ingredients should follow in the future. The fourth group, tooth desensitizers, contains several agents that were almost approved. The status of ingredients in each of these categories is contained in Table 1. Each ingredient will be discussed in this lesson.

TABLE 1 FDA Advisory Panel Rulings on Active Ingredients in OTC Drug Products for Relief of Oral Discomfort*

Nucosal Analgesics
Category I Benzocaine (5-20%)
Butacaine (4%)
Phenol (0.25-1.5%)
Sodium phenolate
(0.25-1.5%)

Category II Camphor
Methyl salicylate
Category III Benzyl alcohol

Cresol Thymol

Mucosal Protectants

Category I Benzoin (10-20%) Category II None Category III Myrrh

Tooth Densitizers

Category I None Category II Sodium fluoride,

strontium chloride, and EDTA (combined)

Category III Citric acid/sodium citrate
in poloxamer 407
Fluoride salts
Formaldehyde
Potassium nitrite

Strontium chloride

Toothache Remedies

Category I Eugenol (85-87%) Category II Capsicum

Menthol Methyl s

Methyl salicylate Category III Benzocaine

Benzocaine
Benzyl alcohol
Butacaine
Creosote
Cresol
Eugenol (1-84%)

Phenol Thymol

Category I - safe and effective
Category II - proposed to be banned
from future sale

Category III - needs more study before final ruling can be made

Oral Mucosal Analgesic/ Anesthetics

The oral mucosal analgesics are intended for short-term use to provide relief of pain, until the lesion heals, or until more definitive treatment can be initiated by a dentist or physician. Those agents most commonly used are benzocaine, butacaine, aromatic alcohols (i.e., eugenol), and phenol and its derivatives.

Benzocaine has been the most widely used anesthetic agent because it is effective in low dosage. Even in high concentrations, serious toxicity problems are unlikely. It is also nonirritating to tissue unless the individual is allergic to it. Benzocaine has an almost immediate onset of action, and relatively short duration of action. This can be lengthened somewhat by incorporating it in a vehicle such as Orabase^R, which remains in contact with the oral mucosa. It is reported that the painrelieving action of benzocaine is localized to the site of application. Whatever drug is absorbed is insufficient to provide analgesia or anesthesia (and therefore side effects) elsewhere in the body. Benzocaine, as well as the other local anesthetics. appears to act by interfering with the movement of sodium into or out of nerve fibers, and, therefore, interrupts the passage of pain impulses through the affected area to the brain.

It has been used widely since the turn of the century with no significant reports of toxicity. However, drug-induced methemoglobinemia may occur in infants following high doses of benzocaine suppositories. Thus, the use of benzocaine-containing products in infants under six months is not recommended.

Butacaine is as effective as benzocaine, but reportedly more toxic. It, too, has a long history of safe use. However, since it has a potential for causing toxicity reactions in high dosages, FDA limited its availability to 0.75 to 4% concentrations. The FDA advisory panel reporting on oral discomfort agents has suggested that butacaine be available in single use units, with no more than six units per package. It also recommended that a warning to consumers appear on the label advising them

not to use more than one unit at a time, no more frequently than one every three hours, and not to exceed three doses daily. Additionally, the label should warn against use for teething pain in infants.

Phenol and sodium phenolate (0.25 to 1.5%), in a hydroalcoholic solution containing up to 20% alcohol, is an effective dental rinse. Phenol and sodium phenolate, with alcohol in concentrations up to 70% for direct application, are effective oral mucosal analgesics. Higher strengths are too irritating, and possibly corrosive.

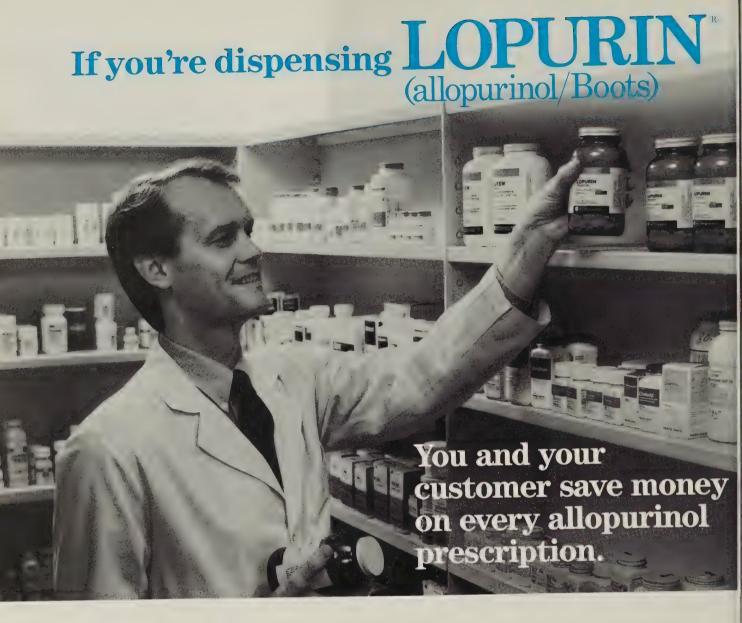
Benzyl alcohol, cresol, and thymol have some, but insufficient, evidence of effectiveness on the oral mucosa. They have demonstrated local anesthetic activity on skin, but controlled studies on their safety and effectiveness when applied to the oral mucosa are needed.

Camphor and methyl salicylate have been ruled "unsafe" as oral mucosal analgesics. The concern for accidental ingestion of camphor is too great, in the opinion of the FDA advisory panel. (Camphorated oil was removed from the OTC market just prior to this panel submitting its report.) Methyl salicylate, also frequently included in analgesic balms for application to the skin, is too irritating for application to oral mucosa. Both of these agents may be included in low concentrations for their flavoring properties.

Oral Mucosal Protectants

Oral mucosal protectants are defined as adherent, flexible, insoluble, pharmacologically inert substances which form a continuous, semirigid coating that protects the area from further irritation by chewing, swallowing, etc. They can provide temporary relief of discomfort from minor thermal and chemical burns, irritations, traumatic ulcerations or canker sores.

Benzoin preparations (the tincture and the compound tincture) have demonstrated sufficient proof of safety and effectiveness to be placed in Category I. In the treatment of oral lesions, the area should be dry (benzoin is not water soluble) before applying the product. This provides a transient protective coating.



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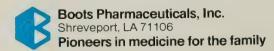
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Neither product should be diluted because this reduces its effectiveness as a protectant. It should not be applied more often than every two hours. The advisory panel suggested that it be packaged in 30 ml sizes or less, and that they have child resistant caps.

Although tincture and fluid extract of myrrh have been applied to oral tissue for the same use for many years, the panel could not find documented evidence of effectiveness. Therefore, such studies will be required before it can be officially considered for this indication.

OTC Tooth Desensitizers

Tooth (dentin) desensitizers are inlicated for treating ultrasensitive eeth. Dentin, the calcified tissue hat composes the bulk of the tooth. contains the tooth's sensory apparaus. Normally, dentin is protected by enamel on the crown of the tooth and cementum at the root. When these wo highly calcified structures are ost due to erosion, abrasion, caviies, chipping, or other causes, the exposed dentin can become sensitive o various stimuli including chemials, heat, cold or touch. Agents that re claimed to provide tooth lesensitization include fluoride alts, strontium chloride, potassium litrate, and formaldehyde.

The panel could not formally rule n agents used as tooth desensitizers or several reasons. Consumers cannot self-diagnose dental hypersensitivity or its cause, because the exact nechanism of action of dental ypersensitivity is not yet known. Ilso, the means of evaluating esensitizing agents is more subjec-

ve than objective.

However, the advisory panel sugested that the items mentioned hove are useful in providing tempotry relief until professional help can obtained. Also, they are approprite for use after the condition has ben correctly diagnosed and repair ork has been made. The panel left te door open for continued OTC ailability of tooth desensitizers by acing them in the "needs more idy" category. They are all safe for TC marketing, but of questionable ficacy for self-use. Manufacturers products containing them must w prove this effectiveness.

OTC Toothache Remedies

Toothache remedies provide temporary relief of pain caused by an open tooth cavity. There are two types — those applied to the open cavity and those applied to the adjacent gum via a poultice. These agents are controversial. Some representatives of the dental profession have expressed concern that their effectiveness is doubtful. However, the FDA advisory panel feels that safe and effective toothache remedies have a place in the OTC market, so that consumers have medication available until professional help can be obtained.

When dental pulp is exposed to irritation, intense pain and inflammation can result. This inflammation may be reversible, which is correctable, and irreversible, which renders the tooth nonviable. Dehydration of dentin is one factor which contributes to the formation of irreversible inflammation. Since this can be caused by medications containing alcohol (20% and above), they are contraindicated for use as toothache remedies.

It is also considered irrational to place an occlusive substance, such as wax, gum, paraffin or cotton (with or without medication) into the tooth cavity. This may result in intensified pain and spread of infective organisms into the deeper areas of the tooth, socket or general circulation.

Even though substances such as beeswax, paraffin and sandarac (an alcohol soluble, water insoluble resin) that are applied to cotton pellets have been used in open dental cavities for years, FDA believes that the risks associated with occlusion do not warrant continued OTC availability of these items. Sandarac solutions in alcohol are especially dangerous since the high levels of alcohol could dehydrate the dentin and destroy the tooth. Only dentists can apply this product safely.

The panel that reviewed these agents also expressed concern about poultice dosage forms because they may cause further irritation to the damaged mucosa. Additionally, they could be erroneously instilled into dental cavities, and might be accidentally swallowed resulting in systemic effects. While there is insuf-

ficient scientific evidence that counterirritants contained in poultices actually relieve toothache, numerous empirical observations and testimonials suggest that these agents are useful. Supposedly, by irritating the oral mucosa around the aching tooth, the sufferer's perception of deep-seated dental pain is alleviated. Since both types of pain may travel along the same neurons, the possibility exists that poultices work. Additionally, the placebo effect of placing a poultice near a sore tooth is very real. The panel concluded that, with proper warnings to prevent misuse, dental poultices should remain available OTC, provided that their manufacturers prove the active ingredients are safe and effective.

Of the dozen or so substances reviewed by the FDA advisory panel, only eugenol (clove oil) in an 85 to 87% concentration has sufficient documented proof of safety and effectiveness with proper labeling. There is a potential safety problem because eugenol is sufficiently irritating to damaged viable pulp. Eugenol should not be used for pain due to reversible pulp damage which is characterized by intermittent pain of varying intensity. Eugenol should be used only for pain caused by already irreversibly damaged pulp, i.e., that resulting in persistent, throbbing pain. Eugenol acts by a local anesthetic action on the nerve fi-

Eugenol concentrations less than 85% were placed in the "needs more study" category since there are insufficient data to prove effectiveness. Benzocaine and butacaine were also placed in this category. Even though they have been proved effective as oral mucosal analgesics, they have not been proved effective when instilled into a tooth cavity. Benzyl alcohol is also included in this group.

Phenolic compounds including cresol, creosote, thymol, and phenol itself have demonstrated anesthetic activity (they paralyze sensory nerves), counterirritant effects, and germicidal action when applied topically. However, they were placed in this category because none has yet been proven effective when applied inside a tooth cavity.

Safety is another important consideration. At full strength, the phe-

nolic compounds are too corrosive and dangerous to use. However, at strengths of 0.25 to 1.5% for creosote, 0.25 to 1.0% for cresol, and up to 1.5% for phenol, all are safe and effective topical anesthetics when applied to unbroken skin or mucous membranes. Should their sponsors eventually be able to prove the same for application into tooth cavities, the substances will be approved for use as toothache remedies.

Thymol is included in many mouthwashes. Dentists use it mixed with phenol and camphor to prepare cavities before filling, and mixed with zinc oxide to form a protective cap for teeth. It has been used as an OTC toothache remedy, but definite proof of effectiveness has not yet been demonstrated.

Capsicum was assigned Category II status as a counterirritant to be applied to healthy oral mucosa. It is considered to be unsafe for application to damaged mucous membranes or directly into the cavity because it is too irritating. It can actually injure viable dental pulp.

Menthol and methyl salicylate were ruled to be unsafe for use as toothache remedies for the same reasons mentioned earlier. As with oral mucosal analgesics, they can be included in low concentrations for flavoring purposes. At strengths adequate to produce their local anesthetic effect, they are too irritating, and, therefore, unsafe.

Consumer Advice

Assuming that some or all of the drugs that require more studies are eventually proven to be safe and effective for the four indications reviewed, pharmacists can provide advice on their proper use. The published indications and warnings for each group are listed in Table 2.

Regarding the oral mucosal analgesics, benzocaine should be applied to the affected area three to four times a day, unless directed otherwise by a physician or dentist. There is no medically unsupervised recommended dosage for treatment of children under four years of age. Butacaine, if it is approved, will be available in unit dose containers (up to 30 mg.), indicated for a single treatment. It should be applied no

TABLE 2

Proposed Label Statements and Warnings for OTC Drug Products for Relief of Oral Discomfort

Mucosal Analgesics

Indications for the temporary relief of: pain due to minor irritation or injury of soft tissue of the mouth; dental procedure dentures or orthodontic appliances, recurring canker sores when the condition ha been previously diagnosed by a dentist, or sore gums due to teething in infants an children 4 months of age and older.

- Do not use longer than 7 days.
- If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.

Do not swallow.

Do not exceed recommended dosage.

Do not use this product if you have a history of allergy to local anesthetics such procaine, butacaine, benzocaine, or other "caine" anesthetics.

For products containing butacaine sulfate:

Do not use in children under 12 years of age unless recommended by a denti or physician.

Do not use more than one unit at a time. h)

Do not repeat more often than every 3 hours.

Do not exceed 3 doses daily.

For products indicated as teething remedies: "Fever and nasal congestion are no symptoms of teething and may indicate the presence of infection. If these sympton persist, consult your physician."

Mucosal Protectants

- Indications:
 - Forms a coating over the wound.

Protects against further irritation.

For temporary use to protect wounds caused by minor irritations or injury. For protecting recurring canker sores when the condition has been previously diagnosed by the dentist.

Warnings:

Do not use longer than 7 days.

If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.

Do not swallow.

Do not exceed recommended dosage.

Use in children under 12 years of age should be supervised.

Tooth Desensitizers

- Indications:
 - "To aid in the reduction of painful sensitivity of the teeth to cold, heat, acids, swe or contact.'

Warnings:

Do not continue use after 2 weeks except under supervision of a dentist.

Do not swallow.

Use in children under 12 years of age should be supervised.

Sensitive teeth may indicate a serious problem which needs prompt care by a

See your dentist as soon as possible whether or not relief is obtained.

If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.

Do not exceed recommended dosage.

Toothache Remedies

Indications:

"For relief of throbbing, persistent toothache due to a cavity, until a dentist can seen.

Warnings:

Use only in teeth with persistent, throbbing pain.

Do not use longer than 7 days.

If irritation persists, inflammation develops, or if fever and infection develop, discontinue use and see your dentist or physician promptly.

Do not swallow.

Do not exceed recommended dosage.

Use of this product in children under 12 years of age should be supervised. A dentist must be seen as soon as possible whether or not the pain is relieved.

Toothaches and open cavities indicate serious problems which need prompt attention by a dentist.

more frequently than every three hours, and no more often than three times a day. It should not be used in children under twelve, except when advised by a physician or dentist.

Phenol-containing solutions, used as teething preparations, are recommended only for infants over fourmonths of age, and no more often than six times a day. When used as a dental rinse, the lower age limit is six years and the recommended schedule is up to six times a day.

As far as oral mucosal protectants are concerned, the individual should first dry the affected area with a cotton pledget or cotton tipped applicator. The pledget or applicator should be saturated with the protectant and applied approximately every two to three hours as needed. Tooth desensitizers are best applied with a toothbrush at least once a day, following normal brushing.

For toothache remedies, the individual should rinse the tooth to re-

move any food or debris from the cavity. A cotton pledget should be moistened with one to two drops of medication, placed in the cavity for approximately one minute, and removed. Adjacent areas should not be touched with the product. This procedure can be repeated up to four times a day.

Taxes

by Jo Ann Zito, CPA Comprehensive Accounting Services Towson, Md.

The business use of your car allows you to deduct the ordinary costs of operating your vehicle and depreciation against your income.

You are entitled to deduct the business portion of your actual expenses for insurance, gas, repairs, maintenance and depreciation. Under the new system of cost recovery, an automobile is depreciated over three years using an accelerated method incorporated in the law, or straightline if you so elect. The first year's depreciation is 25% of cost, regardless of when during the year the auto was acquired. In the second year, the depreciation is 38% of cost. In the third year, the depreciation is 37% of cost.

In lieu of using the actual cost method, you can elect to use the optional flat deduction which is 20.5¢ a mile for the first 15,000 business miles per year and 11¢ for business miles in excess of 15,000.

Under either method, you are entitled to take a 6% investment credit on the cost of your automobile used in your business. The credit is allowed in the year of purchase no matter when the car was purchased during the year. The investment credit is a direct reduction of your taxes and is available providing that the automobile has a useful life of at least three years. The investment credit for an automobile is 6% of the cost. The cost of the automobile must be reduced by 50% of the investment credit for purpose of depreciation. Thus if the automobile cost 10,000 and it is used 60% of the time for business, the investment credit will be \$360. The cost of the automobile for depreciation will be

\$6,000 less \$180, or \$5,820. Alternatively, you can elect to reduce the credit by two percentage points, from 6% to 4%, in lieu of the basic reduction.

With the rising costs of gasoline and automobile repair expenses, it is important that you maintain actual records to compare the costs of operating your vehicle (including depreciation) with the optional flat depreciation method allowed and to select the method which provides the greatest tax benefits for you.

Award Established

The Dr. Paul Jablon Research Award in Pharmaceutics has been established at the University of Maryland School of Pharmacy by Leon Jablon and the late Yetta Jablon in memory of their son, a 1962 Pharmacy School graduate. Dr. Jablon, who received his Ph.D. degree in industrial pharmacy from Purdue University, was an associate professor at the Albany College of Pharmacy at the time of his death.

Dr. Ralph Shangraw, chairman of the UM department of pharmaceutics, will recommend the first awardee for the fall '85 semester, noting that he or she will be an undergraduate or graduate student "who displays exceptional promise in the field of pharmaceutics." The \$10,000 Jablon fund will be administered by the Pharmacy School dean.



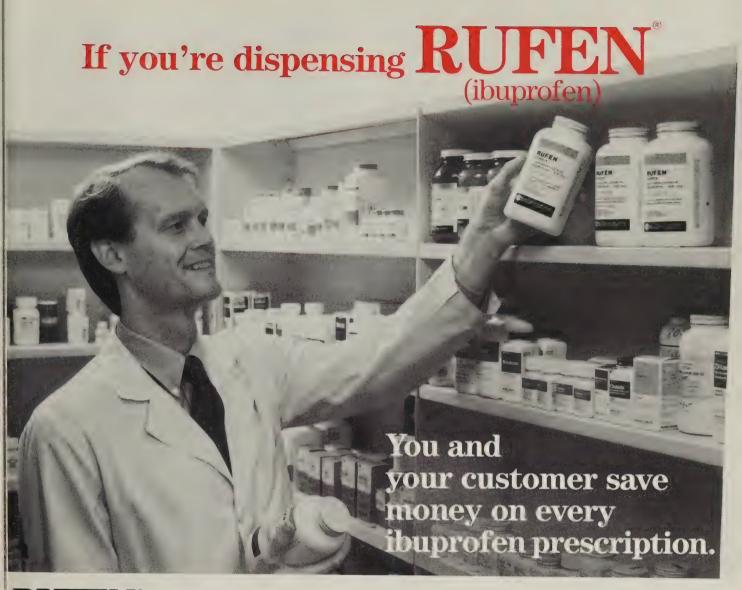
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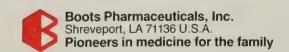
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This and That About Pharmacy

by Leon Weiner P.D.

Spotlight on Clarence Leroy Anstine

Sometime in early March 1985, I spoke to Earl Anstine on the telephone about his desire to locate Trol, a product used for the hair but probably discontinued many years ago. If you have any of this product or know where it can be gotten, please call Earl at 301-486-7550.

Clarence (Bob) Anstine, a graduate of University of Maryland 1958, is his brother and of course, I asked about him. After living in England for a few years, Bob is now living in Marietta GA. I have always been impressed with Clarence because he is an all around guy. While in school and being a class officer, he was active in practically everything. He is also a very interesting writer, probably due to the teachings of Dr. Adele B. Ballman, who was Assistant Professor of English while Bob was at Pharmacy School. Following is Bob's own story about his life before and after Pharmacy School.

A PHARMACIST IN A BOWLER HAT

By C. L. (Bob) Anstine

The mate cast off the line and signaled to the Captain. The engines of the old ferry throbbed to life and churned the icy waters of Naragansett Bay.

As Clay Warrington and I looked ahead to Newport, Rhode Island, I could not then foresee that the line so casually cast off would bring such changes to the life I thought was laid out for me.

Born and raised in Baltimore, I had grown up in drugstores. My pharmacist uncle had owned Anstine's Drug Store on the corner of Monroe and Lexington for years. And my father also owned one in Pimlico—a long time ago.

So it was all settled, in September 1954, I entered pharmacy school to graduate in '58 and follow in their footsteps. The process which changed my direction was the ferry ride to Naval O.C.S. The training resulted in a commission as an Intelligence Officer in the aviation branch of the U.S. Navy.

Trained as Navigator on a P2V aircraft, I served in



Bob and wife Cecelia in the great hall at Timbers. Walls are waffle and daub construction.

an anti-submarine squadron and as Instructor in the Naval Air Intelligence School. These experiences opened the rest of the world to me. The rigors of the work demonstrated the validity of Dean Foss' welcoming words: "The training you receive in Pharmacy School prepares you for life. You may not *know everything*, but you will know where to look for answers."

Leaving the Navy in 1962, I became a Salesman for Eli Lilly and Company. In the fifteen years I spent with Lilly I was on the team that marketed Keflex, helped start Dista Products Company and finally became Sales Manager in Atlanta, Georgia. But my wife Cecelia, my son Hunter and I were not reaching our goal—to live in Europe.

A call from an Executive Recruiter changed all that. In 1980 I became General Manager, U.K., for Whittaker Life Sciences, Ltd. With offices in London, Dublin, Copenhagen, Beirut and Sydney, Australia; our task was to supply professional and other personnel to Whittaker managed hospital projects in Saudia Arabia and the Emirates.

The first problem—where to live—was solved when we were introduced to a 300 year old cottage in Chobham, Surrey, about 25 miles south of London. A black and white Tudor house on the edge of a village with roots going back to the year 900.

Formerly the home of Mrs. Pankhurst (the suffragette) and Merle Oberon (the actress) *Timbers*, Bagshot Road, was straight out of a movie set. It had originally been a smoke column house. No fire place and the smoke from the ever present fire formed a column of smoke which rose through the rafters and out openings at the ends of the roof. Thank goodness we weren't there in 1610 when it was new.

The house came equipped with Reg the Gardner. Reg ran the garden in such a way that there was something blooming 12 months of the year. And did it bloom. Roses, heather and even broccoli. Up until then I thought broccoli grew in small freezer boxes!

The job was interesting as well. Each morning I caught the 6:55 from Sunningdale and rode British Rail to Waterloo Station. Short jaunts on the Bakerloo and Picadilly Lines of the London Underground deposited me in Knightsbridge and my office between Hyde Park and Harrods.

Frequent trips to places I had only dreamed about maintained the pace. Where once I had dined graciously in the lunch room at the old Greene Street Pharmacy Building, I now flew to Paris for lunch. Where once I had shopped in the bazaar of Towson Plaza, I now shopped in the mysterious Gold Souks of Jeddah.

And the job was rewarding. In the Middle East many people cook with propane gas. In 120° heat that means house fires and house fires mean casualties. One service that I coordinated was the hospital plane that brought serious burn patients to London for treatment.

The phone would raise me from sleep at 3 A.M. A few quick notes and then the day began. Ambulances to meet the jet at Heathrow, reception ready at the hospital, everything to proceed like clock-work. Joyously it did. We didn't lose one patient who made it to London.

Growing up in Maryland I never classified my friends as to race, religion or other meaningless categories. This attitude evoked one of my most exciting experiences while in London.

Part of my job was to maintain relationships with the London ambassadors of both the Kingdom of Saudi Arabia and Dubai. One day I was to take a film which we had produced on our operations in KSA to Suliman, the Consul General, in the Saudi Embassy.

The film had been brought to me from our headquarters in California by Barney Ward, a corporate official. I thought that Barney might like to meet the Consul so I arranged for him to accompany me.

Our cab pulled up to the Embassy, we got out and I pushed the large button to signal the doorkeeper. As we stepped through the metal detectors and I turned to introduce Barney to Aziz, the doorkeeper, a cold chill went up my spine. I suddenly remembered—Barney happens to be Jewish and I was taking him to the depths of an Arab Embassy.

My fears abated when Barney and Suliman chatted like old friends. Barney even called him "Sul." If heads of state could only meet like that our problems would be minimized—just Barney and Sul talking together.

After several years in London we returned to Atlanta where I am now Vice President of a human resources marketing company. Cecelia volunteers as a Department Superintendent in a Sunday School and Hunter is trying to perfect his technique in saddle seat riding.

We have a dog—Tinker—who Cecelia bought from the gypsies who lived in a caravan near Timbers. But that's another story for another day.

Pharmacy in the Family

Case I: I recently met Mary Paula Cavoures, P.D., at the Rite Aid Drug Store at Eastpoint Shopping Center in Baltimore County. She is a graduate of the University of Maryland Pharmacy School in 1983. After some conversation, it became very apparent that she was very happy being a pharmacist and also very proud of her older brother. James Anthony Cavoures, P.D., graduated from the University of Maryland Pharmacy School in 1965 and is now working for K-Mart Drugs. There is no doubt that he was the inspiration that made Mary graduate from pharmacy school 18 years later.

Case II: John Joseph Imwold, Sr., knows pharmacists inside and out. He should because he has been a traveling drug salesman for close to 40 years. First, he worked for Gilpin Drug Company and then with Drug House when they acquired Gilpin. Therefore, his sons grew up at home with lots of pharmacy talk. In spite of this, Charles (Chuck) Imwold graduated from the University of Maryland Pharmacy School in 1977 and is now working for Giant Pharmacies. Then, in 1984, John Joseph Imwold, Jr. graduated from the University of Maryland Pharmacy School and is currently employed by Howard and Morris, Pharmacists.

Ervin M. Koch, P.D., is the very popular owner of Tenley Pharmacy in Rockville, MD. Born in St. Louis, MO, he graduated from the St. Louis College of Pharmacy in 1952. During the Korean conflict, he was drafted into the Marine Corps where he was stationed at Camp LeJeune, NC and then the Marine Corps Institute in Washington, DC. After being discharged, he decided to remain in the Washington, DC area and worked at various times for Bretler's Pharmacy, Coral Hills Pharmacy, and Chandler Drug Company before becoming a drug salesman for Upjohn Company in 1959. In 1964, Ervin had the opportunity to purchase Tenley Pharmacy, 50 W. Edmonston Drive, Rockville, MD, which he did, and he has now completed 20 years as the likeable pharmacist-owner.

Dr. Koch was married in 1953 while he was in the Marine Corps and is the proud father of two boys and three girls. At the present time, three of his children are in college. One is his daughter, Sandra, who is studying pharmacy also at the St. Louis College of Pharmacy and is hoping to graduate in 1987.

Ervin was the president of the Prince Georges-Montgomery Pharmaceutical Association in 1968. When not working, he spends much time at the Argyle Country Club where he a good golfer with a 10 handicap.

Deceased Alumni

Since June 1984

The official list of Deceased Alumni, University of Maryland, School of Pharmacy, has been compiled by Margaret Beatty, Administrative Aide, School of Pharmacy. If you have any additions, please contact her at (301)-528-7650.

Name	Degree	Year
Davis M. Bishop	B.S.	1952
Stanley Brodie	B.S.	1951
Alton L. Geesey	Ph.G.	1930
Leon Goodman	B.S.	1941
Louis R. Kern, Jr.	B.S.	1962
Jacob Kronthal	Ph.G.	1924
Antoinette M. Lauten	B.S.	1959
Earl H. Lightner	Ph.G.	1916
Comuci Markin	Ph.G.	1933
Michael Patton	B.S.	1977
Ferdinand Pross	Phar.D.	1914
Daniel A. Santoni	Ph.G.	1933
Abraham Schapiro	Ph.G.	1930
Jacob Serpick	Ph.G.	1925
Theodore E. Stacy, Jr., M.D.	Ph.G.	1923
Solomon Stichman	Ph.G.	1928
George J. Stiffman	Ph.G.	1931
Alexander Tucker	Ph.G.	1934
Alexander rucker		



A Christmas Greeting in the Summer

Above is a picture of the men of the Division of Drug Control as they got together for their Christmas 1984 luncheon. From left to right are Charles H. Tregoe, Leon Weiner, Jack Freedman, Raymond Lichter, Bob Chang, John O'Hara, and Bill Hahn. Mr. Tregoe is the Chief of the unit and his assistant is Mr. O'Hara. Unfortunately, Thomas Kelly is missing.

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Eli Lilly and Company Indianapolis, Indiana 46285 ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN REFINEMENT, PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPM, LENTE*, ETC.), AND/OR METHOD OF MANUFACTURE (RECOMBINANT ONA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.

GATEWAY I SINGLE POINTS OF CONTACT

From the MPhA and the Elder Ed Program

If you need information or services for the elderly, get in touch with the office listed below in your area.

SERVICES AND BENEFITS AVAILABLE FOR THE ELDERLY IN MARYLAND

HOUSING:

- Low Cost Housing
- Tax Relief—Homeowners/Renters
- Weatherization/Home Repair
- Fuel Assistance
- Continuing Care

HEALTH:

- Medicare and Medigap Insurance
- Pharmacy Assistance
- Nursing Home Information and Complaints
- Medicaid

FOR FRAIL ELDERLY:

- Sheltered Housing
- Day Care and Home Care
- Meals on Wheels
- Nursing Home Care
- Needs Assessment

INCOME FINANCIAL AID

- Social Security
- SSI
- Pensions
- Food Stamps : # 352 PAGE
- Unemployment Insurance
- Tax advice and preparation
- Discount Cards
- Veterans Benefits

COMMUNITY SERVICES

- Senior Citizens Centers
- Daily Meals
- Volunteer Work

OTHER:

- Transportation
- Employment
- Legal Services
- Protective Services/Guardianship
- Physical Fitness
- Education

IF YOU LIVE IN: CALL YOUR GATEWAY TELEPHONE:
ALLEGANY COUNTY Cumberland Senior Citizens Center 19 Frederick Street Cumberland, Maryland 21532
ANNE ARUNDEL COUNTY Arundel Center North 101 Crain Highway, N.W. Glen Burnie, Maryland 21061 1-800-492-2499
BALTIMORE CITY Waxter Center for Senior Citizens 861 Park Avenue Baltimore, Maryland 21201
BALTIMORE COUNTY Baltimore County Department of Aging 611 Central Avenue Towson, Maryland 21204
CALVERT COUNTY Calvert Pines Senior Center 450 West Dares Beach Road Prince Frederick, Maryland 20678 Southern—local number
CAROLINE COUNTY Caroline Senior Center 4th Street Armory Denton, Maryland 21629
CARROLL COUNTY Westminster Senior Center Old West End School Building Schoolhouse Avenue

Westminster, Maryland 21157

Charles County Aging Services Office

CHARLES COUNTY

P.O. Box B

from Baltimore876-3363, Extension 21

from Mt. Airy875-3342

Westminster848-4049

La Plata, Maryland 20646934-8080

Cecil Senior Center Holly Hall
703 South Bridge Street P.O. Box 1182
Elkton, Maryland 21921
DORCHESTER COUNTY Cambridge MAC Center 420 Muir Street
Cambridge, Maryland 21613
Frederick County Commission on Aging 520 North Market Street Frederick, Maryland 21701
GARRETT COUNTY
Oakland Senior Center 104 East Center Street
Oakland, Maryland 21550
Grantsville, Maryland 21536
HARFORD COUNTY Harford County Senior Center 140 North Hickory
Bel Air, Maryland 21014 Harford
HOWARD COUNTY Howard County Office on Aging Florence Bain Senior Center 5470 Beaverkill Road
Columbia, Maryland 21044
KENT COUNTY County Office Building 400 High Street Chestertown, Maryland 21620
MONTGOMERY COUNTY Holiday Park Senior Center 3950 Ferrara Drive Wheaton, Maryland 20906
PRINCE GEORGE'S COUNTY Office on Aging 5012 Rhode Island Avenue
Hyattsville, Maryland 20781
QUEEN ANNE'S COUNTY Queen Anne's County Office on Aging Annex Building Banjo Lane
Centreville, Maryland 21617
SOMERSET COUNTY Project Gateway 424 North Somerset Avenue

Princess Anne, Maryland 21853651-0020

ST. MARY'S COUNTY Garvey Senior Center Box 351 Leonardtown, Maryland 20650	75-5100
TALBOT COUNTY Talbot County Health Department 100 South Hanson Street P.O. Box 480 Easton, Maryland 21601	22-6828
WASHINGTON COUNTY Washington County Commission on Aging Alexander House 9 Public Square Hagerstown, Maryland 21740	
WICOMICO COUNTY Pine Bluff MAC Center 1504 Riverside Drive Salisbury, Maryland 21801	3-0388
WORCESTER COUNTY Snow Hill MAC Center P.O. Box 150 107 East Market Street Snow Hill, Maryland 21863	2-1289

GATEWAY II

What is Project Gateway II?

GATEWAY II is the coordinated system of community services provided jointly by the local Office or Department on Aging, the Social Services Department, the Health Department, and other agencies.

GATEWAY II helps frail health-impaired older persons select and locate the services that can help them to continue to live in their homes and stay in their communities.

What Will Gateway II Do?

An older person who has chronic health problems may need services from several public and private agencies. The older person may need help to arrange these services.

Local agencies work together to determine which services are needed. An evaluation of needs is done in the home, by a qualified staff person or team, usually from Geriatric Evaluation Services. After the needed services are identified, a GATEWAY II case manager will help locate and arrange for the services. The case manager may be from the local Office/Department on Aging, the Social Services Department, the Health Department, or another community agency. The case manager will insure that the older person receives the right services at the right time. GATEWAY II has some funds

available to help pay for gap-filling services for persons who meet financial and other eligibility criteria.

Who Can Get Help from Project Gateway II?

To be eligible, a person must

- Be 65 years of age or older
- Need assistance with several daily activities, such as bathing, dressing, preparing meals, etc.
- Be medically at risk of institutionalization.
- Live in one of the local areas where GATEWAY II now operates.

Such persons may be eligible for gap-filling service dollars if they meet established financial standards and other eligibility criteria.

Where Do Referrals for Gateway II Come From?

Referrals come from many sources, including older persons themselves, family members or friends, physicians, hospital staff, home health agencies, local public agencies, etc. In fact, anyone can make a referral to GATEWAY II.

Where Does Gateway II Operate?

Currently, GATEWAY II operates in nine jurisdictions in Maryland. Some projects have waiting lists of persons to be served.

To find out more about the project's services or to seek assistance, contact the local GATEWAY II office. Or, for more information, contact the Maryland Office on Aging at (301) 383-2100.

LOCAL GATEWAY II OFFICES

Anne Arundel County

Anne Arundel County Health

Department

Phone: 1-800-492-2499

Baltimore City

Baltimore City Area Agency on Aging

Phone: 396-1605

Baltimore County

Baltimore County Department on Aging

Phone: 494-2594

Harford County

Harford County Office on Aging

Phone: 838-2552

Howard County

Howard County Health Department

Phone: 992-2333

Montgomery County

Montgomery County Department of

Social Services Phone: 468-4240 Prince George's County

Prince George's County Health

Department

Phone: 386-0130

Talbot County

Talbot County Health Department

Phone 822-6828

Washington County

Washington County Commission on

Aging/Area Agency on Aging

Phone: 790-0275

PHARMACY CHANGES—March 1985

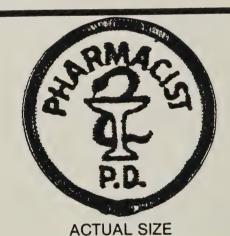
The following are new pharmacies:

Peoples' Drug Store #1163 Osborne Shopping Center 7500 block Robert Crain Hwy. (Rt. 3) Upper Marlboro, MD 20870

Medicine Shoppe 7604 Baltimore-Annapolis Blvd. Glen Burnie, MD 21061

The following is a change of ownership:

Parker's Olney Pharmacy 3470 Olney-Laytonsville Rd. Olney, MD 20832



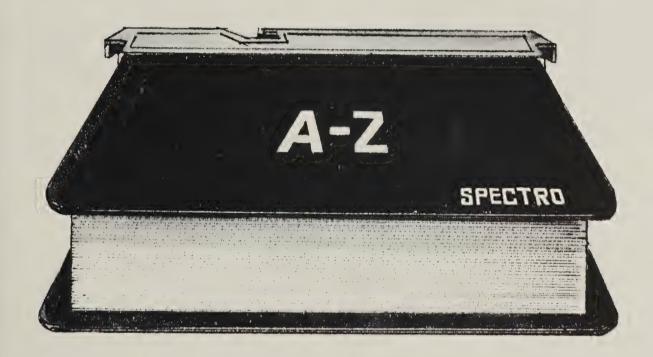
Pharmacist Insignia PATCH NOW AVAILABLE

The new emblem for pharmacists utilizing the "P.D." designation has arrived. Designed to be sewn on dispensing jackets, these new insignia are embroidered in dark blue with a white background, and cost \$1.50 each.

To order, send check or money order for emblems @ \$1.50 each to:

Maryland Pharmaceutical Assn. 650 W. Lombard St. Baltimore, Md. 21201

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District Wholesale Drug Corp. Landover, MD 20785 301-322-1100

Loewy Drug Co., Inc.

Baltimore, MD 21237 301-485-8100

THE HEALTH CARE COMPANY



Physician/Pharmacist Code of Cooperation

Acknowledging that the practice of medicine and pharmacy needs the combined services of both groups, this Code of Cooperation is hereby adopted as a declaration of principles of conduct for the two professions to follow. It is clearly understood that local laws, regulations, and Codes of Ethics of both professions clearly take precedence over this code of cooperation.

It is the hope of the two professions that the adoption of this Code of Cooperation will result in an improved understanding and closer relationship between the professions of medicine and pharmacy in the interest of better health care.

Physicians

The Medical and Chirurgical Faculty of the State of Maryland believes that drug dispensing by physicians should be discouraged if adequate pharmaceutical service is available. A physician's professional source of income should be from the services he renders to his patients, and only from this source.

Physicians collectively, through the Medical and

Chirurgical Faculty, recognize the following:

1. A patient should be permitted the free choice of his pharmacy, just as he should be permitted free choice of physician.

2. Physicians should not advise a patient as to the charge for professional pharmaceutical service.

- 3. The physician should cooperate with a pharmacist by specifying the number of times a prescription is to be refilled, and by making himself available to the pharmacist to determine whether or not his original orders should be altered after the original number of refills has been obtained. A prescription should never be marked for a refill contrary to current laws or regulations.
- 4. Physicians may, at their own discretion, indicate on the prescription order they write, that the prescription label include the name of the drug ingredients, as well as any other information deemed necessary.

This is an individual decision and one that will depend upon the expert judgment of the physician based on the patient as an individual (H of D 5/64)

5. Physicians should not dispose of drug samples to pharmacists for any consideration, either direct or indirect. The use of drug samples in a physician's practice should be done in a manner that recognizes the position of the pharmacist in his role as a provider of drugs to the public. It is the responsibility of the physician to dispose of any undesired drug samples only through

destruction, disposition to organizations or through the approved program of the Auxiliary of the local medical societies. In no event should such drug samples be disposed of in a manner that would permit their falling into the hands of unauthorized persons.

6. Physicians should not enter into any rental, ownership, or financial agreements or any other activity with pharmacists that would directly or indirectly affect the prescribing of medication by a physician in favor of a particular pharmacy or pharmacies.

7. The patient is always entitled to a written prescription. It is recognized, however, that it is permissible for a physician to prescribe by telephone to pharmacists of the patient's choice rather than writing prescriptions out individually.

8. Sale to patients or others of drug samples which have been given free to physicians, is to be condemned. In general, complimentary drugs should be used only as starter doses. (Council 11/21/61)

9. The use of prescription blanks imprinted with the name of a pharmacist, pharmacists, or pharmacy is specifically prohibited by law.

10. Physicians are free to use either the generic or brand name in prescribing drugs for their patients. However, physicians should consult with the pharmacist as a member of the medical team in order to assure that the patient is properly served by being provided with medication of the highest quality.

11. Physicians should not write prescription order in "code."

12. Physicians' bills should include only those charges for professional services rendered by him or under his supervision.

13. When prescription blanks are not imprinted with a physician's name, his name and degree should be printed or typed legibly below his signature.

Pharmacists

Recognizing that pharmacists and physicians must work as a team, the pharmacists, through the Maryland Pharmaceutical Association—the state professional pharmaceutical society—hereby adopt the following principles: It is understood that the foregoing principles for physicians, insofar as they affect the profession of pharmacy, are also subscribed to by the profession of pharmacy. It is also understood that some of these principles are presently incorporated in federal and state laws and regulations as standards and requirements fo pharmacy practice.

Pharmacy, recognizing the inestimable value of the professional pharmacist to the health team, encourages him to fulfill completely the professional requirements of his calling, and desires that he decrease his activities in commercial enterprises which presently may be associated with but are not and should not be related to the practice of pharmacy.

1. Pharmacists, as well as physicians, are obligated to serve the public whenever their services are needed. On nights, Sundays and holidays, prescription services should be readily available in case of emergency.

2. The pharmacist should never diagnose or prescribe, even at the insistence of the patient, but should refer those needing medical attention to a physician of the patient's choice.

3. The sale of proprietary products and home remedies that have been approved by the Federal Food and Drug Administration for over-the-counter sale for self-medication shall not be considered counter prescribing by the pharmacist.

4. If an emergency, or preceding arrival of the physician, the pharmacist will render such emergency treatment as is indicated by his training, experience, scientific knowledge, and good judgment.

5. If there is any question in the pharmacist's mind regarding the ingredients or labeling instructions of a prescription order, possible error or safety of the drug, he should privately and tactfully consult the physician before making charges and never discuss it with, or in the presence of, the patient.

6. The pharmacist shall be responsible for providing a comprehensive supply of drugs on which the physician may draw by prescription order for the treatment of his patient and serve as a source of information on new drugs and their combinations in order that the physician and his patient may have the advantage of the latest pharmaceutical developments.

General

Neither physicians nor pharmacists should approach each other with respect to the completion of illegal arrangements, such as pharmacists working as an employee of a physician. Pharmacists shall not engage in, and physicians shall not accept, advertising of a pharmacy in a physician's office or waiting room.

The physician has a responsibility to make clear to he patient that even though a specific drug may be expensive, it is the best therapeutic agent he feels can be administered in treating the condition of the patient. Pharmacists, in turn, should not comment on the efficacy of the drug prescribed or of a substitute drug.

Publicity in connection with professional activities of either pharmacist or physicians should be cleared hrough the appropriate professional group. In all cases, news or feature stories affecting both professions hould be developed cooperatively by the two groups.

Congratulations University of Maryland School of Pharmacy

The Class of 1985 Bachelor of Science in Pharmacy

Rebecca M. Aglubat Anne Marie Bartels Eric Baylus Richard C. Benchoff, II Jennifer L. Bickley Kyung S. Choe Pamela J. Cook Randy D. Cutler Debra M. D'Ascenzo Karl R. Deigert Pamela E. Deiss Daniel A. Diggins, Jr. Carolyn J. Dunn Donna A. Falck Sally A. Felton Kathleen L. Gauthier Susan M. Ilioff Martin Jagers In-Ok Jung Thomas Jurasko Ramon B. Juta Jovce A. Kalimon John W. Kamberger Frances G. Kaplan Ki J. Ke Hoon Kim Kyong A. Kim Laura Y. Kim Mihi J. Ko Jay E. Krosnick Theresa M. LaCasse

Robert M. Landsman Frank D. Mackowiak Reda A. Massoud Mark P. McDougall Theodore W. Merrill, Jr. David G. Miller Angela D. Miller-King Charles G. Muendlein, Jr. Francis X. Muller Joseph W. Murray Michele C. Owens Charlene Ozanne Soon H. Park Kathryn L. Parker Michele A. Perry Thomas J. Pfaff Karen B. Presswood Jovce M. Prince Melinda A. Seith Michele L. Shores Sammy J. Speedone* Nancy E. Stavely James R.-Steinberg Sharon L. Taylor Min Than Gail L. Ulanow Andrea D. White Sun M. Yang Sung H. Yi Alex Y. Yung Anthony E. Zimmerman

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James B. Caldwell
Margaret M. Delprete
Anne C. Hom
Jeffrey R. Hout
Karen E. Koch
Sally J. Nuessle
Joseph D. Ober
Constance W. Recupero

^{*} January 1985

Medicaid's New S. and Q. List

Usual Source and Quantity List for High Utilization Drugs

	Maximum	
	Drug Product	Price Basis
		1000
Aldomet 250 mg tablets—Merck, Sharp & Dohme	D .	1000 100
Aldomet 500 mg tablets—Merck, Sharp & Donme	D	100
Aldoril 25 mg tablets—Merck, Sharp & Dohme	D	100
* Ativan 1 mg tablets—Wyeth	D	
* Ativan 2 mg tablets—Wyeth	D	100
* Clinoril 150 mg tablets—Merck, Sharp & Dohme	D	100
* Clinoril 200 mg tablets—Merck, Sharp & Dohme	D	100
* Cogentin 1 mg tablets—Merck, Sharp & Dohme	. D	100
* Cogentin 2 mg tablets—Merck, Sharp & Dohme	D	100
* Cogentin 2 mg tablets—Merck, Sharp a Somme	W	500
Darvocet N 100 tablets—Lilly	D .	100
Diabinese 250 mg tablets—Pfizer	D	1000
Dilantin 100 mg capsules—Parke-Davis	D	240 ml
* Dilantin—125 suspension—Parke-Davis	D	60
* Dolobid 500 mg tablets—Merck, Sharp & Dohme	D	100
* Foldene 20 mg capsules—Pfizer	- D	100
Indocin 25 mg capsules—Merck, Sharp & Donme	D	100
Indocin 50 mg capsules—Merck, Sharp & Donme	D .	60
* Indocin 75 mg SR cansules—Merck, Sharp & Donnie		10 ml
* Isophane Insulin Suspension U100 (NPH Insulin)—Squibb	D.	30
* K-Lor 20 mEd packets—Abbott	D	
* Lanoxin 0.125 mg tablets—Burroughs Wellcome	W	1000
Lanoxin 0.25 mg tablets—Burroughs Wellcome	W	1000
* Lo/Ovral tablets—Wyeth	D	6 × 21
* Lo/Ovral-28 tablets—Wyeth	D	6 × 28
LO/Ovrai-20 tablets—wyeth	D	250
* Minipress 1 mg capsules—Pfizer	D	250
* Minipress 2 mg capsules—Pfizer	D	250
* Minipress 5 mg capsules—Pfizer	D	500
* Motrin 600 mg tablets—Upjohn	D	6 × 21
Ovral tablets—Wyeth	D	6 × 28
Ovral-28 tablets—Wyeth	D	pint
* Phenergan syrup, plain—Wyeth	D's	pint
* Phenergan with Codeine syrup—Wyeth	D	pint
* Phenergan VC syrup—Wyeth	D	pint
* Phenergan VC with Codeine syrup—Wyeth	D or W	1000
* Phenoharbital 15 mg tablets—all manufacturers	D or W	1000
Phenobarbital 30 mg tablets—all manufacturers	D OI W	100
* Procardia 10 mg capsules—Pfizer	D	30 ml
* Rondec drops—Ross		pint
* Rondec syrup—Ross	D	. 30 ml
* Rondec DM drops—Ross	D	
* Rondec DM syrup—Ross	D	pint
* Rufen 600 mg tablets—Boots	M	500
* Tabron tablets—Parke-Davis	D	100
Thorograp Hematinic tablets—Squibb	D	90
* Timoptic 0.5% Sterile Ophthalmic solution—Merck, Sharp & Dohme	D	5ml,10ml,15ml
Tolinase 250 mg tablets—Upjohn	D	100
Tollinase 200 mg tablets Unjohn	D	100
* Tolinase 500 mg tablets—Upjohn	D	100
* Tranxene 3.75 mg capsules—Abbott	D	100
* Tranxene 7.5 mg capsules—Abbott	W	500
Valium 2 mg tablets—Roche	W	500
Valium 5 mg tablets—Roche	W	500
Valium 10 mg tablets—Roche		100
Valium 10 mg tablets—Roche * Xanax 0.5 mg tablets—Upjohn	D D	

Key:

D—denotes manufacturer's direct price

W-denotes wholesaler's price

*-addition (not on previous list)

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Upjohn



ACI Knoil) erapamil Intravenous 5mg 2ml 10 mg |4ml Tablets 80 mg Available in Ampules, Pre-Filled Syringes and and single Dose Vial 120 mg A product of Knoll research Also available in Unit-Dose Strip Packs

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MPhA President Ronald A. Sanford (right) presents Pharmacy Students Lauretta A. Dunn and Ken Krauss (left) with the 1985 Scholarship Awards in front of the Kelly Memorial Building.



Graduating Pharmacy Student, David Miller, served as a special studies Extern in the MPhA office and has recently been hired by the National Association of Retail Druggists for a staff position.



The School of Pharmacy's Alumni Association's Annual Banquet was held May 23, 1985. Board of Pharmacy President Bernard Lachman (left) receives the Honored Alumnus Award from the Chief of the Division of Drug Control, Charles Tregoe (right).



The torch of leadership for the Alumni Association passed from outgoing President Melvin Rubin to incoming President Karen Dempsky at that meeting.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

TIMOLOL:

Beta-adrenergic blocking drugs have been used to treat migraine headache refractory to more conventional drugs. Migraine headache is said to occur primarily in women, and affects from 5 to 25% of those in western society. Timolol was used to determine if it had an effect on this condition. It was noted that timolol does have the ability to reduce the incidence and the symptoms of migraine headache. *JAMA*, Vol. 252, #18, p. 2577, 1984.

SULFINPYRAZONE:

Hyperuricemia has been treated with sulfinpyrazone, a drug which has also been used to prevent platelet inhibition. Its activity seems to outlast the presence of the parent drug thus suggesting that an active metabolite might be formed which produces the beneficial action. Further research shows that an active metabolite of sulfinpyrazone is formed by bacterial flora of the colon. *J Pharmacol Exp Ther*, Vol. 230, #3, p. 726, 1984.

OSTEOMALACIA:

Osteomalacia was described as more than 25% of trabecular bone surface in an iliac crest biopsy sample covered with osteoid and a mean osteoid seam thickness of greater than 11 micrometers. Using this definition, osteomalacia was found in 3.7% of the patients sampled. The condition was more prevalent in women than in men, and more in those over the age of 80 years. Lancet, Vol. II, #8399, p. 386, 1984.

ANTACID THERAPY:

Patients with chronic duodenal ulcers or juxtapyloric ulcerations were divided into three therapy groups. One group received 30 ml of an antacid preparation seven times daily, one group received 10 ml of the antacid as necessary, and the third group served as a placebo control. Clinicians found that poor compliance and diarrhea associated with the higher doses of the antacid preparations allowed the lower dose regimen to be clinically superior, and better tolerated. *Br Med J*, Vol. 289, #6449, p. 869, 1984.

SMOKING:

More attention has been given smoking cessation today than ever before. Physicians are starting to "practice what they preach", and are stopping the habit in greater numbers. The nicotine chewing gum has proved beneficial in double blind studies and represents a way in which one serious about stopping can obtain some pharmacological assistance with their endeavor. *JAMA*, Vol. 252, #20, p. 2835, 1984.

AMOSULALOL:

A new drug with both alpha adrenergic blocking activity (alpha-1 specific) and nonspecific beta-adrenergic blocking action is being used experimentally to determine its pharmacokinetic parameters. Amosulalol is well absorbed and is little affected by first pass metabolism. It is said to be more potent than labetolol (Trandate) as an alpha blocker, but less potent with respect to its ability to block the beta-1 adrenergic receptor site. *Clin Pharmacol Ther*, Vol. 36, #4, p. 497, 1984.

BENZODIAZEPINE DETOXIFICATION:

Efforts are being intensified to make prescribers aware of the problems associated with long-term use of the benzodiazepines, especially in situations when the drug was not indicated for long-term administration. However, patients who have been on high dose benzodiazepine therapy for long periods of time experience withdrawal symptoms when they discontinue the drug, so regimens were designed to help reduce the discomfort of drug withdrawal. A group of patients on the detoxification program were using diazepam and were given a loading dose of diazepam which was comparable to 40% of their previous daily dose. Each day the dosage was reduced by 10%. Clinicians feel that this method of detoxification is an effective and safe way to reduce the discomfort of withdrawal from benzodiazepine derivatives. Clin Pharmacol Ther, Vol. 36, #4, p. 527, 1984.

FOOD INTAKE:

Various agents have been found to increase food intake in animals independent of their previous exposure to food. Animals which were apparently satiated will start to eat when tifluadom is administered. Since this substance has some chemical similarities to the benzodiazepine derivatives, it was of interest to see if it interacted with the classical benzodiazepine receptor site in the central nervous system. Using various antagonistic compounds, investigators were able to determine that tifluadom produces its activity independent of its effects on the benzodiazepine receptor. Narcotic antagonists did block the effect; thus supporting a role for the endorphin system in food intake. It is furthe postulated that this effect is mediated through activity at the kappa or mu receptor rather than at the sigma opoid receptor subtype. We now need to work on a druj which will block the desire for food intake. J Pharn Pharmacol, Vol. 36, #10, p. 683, 1984.

SMOKING AND CROHN'S DISEASE:

Crohn's disease is an inflammatory disease of th colon, but its etiology is unknown. A study has suggested that a relationship exists between smoking an

the development of this condition. Older data suggested that non-smokers were more apt to get ulcerative colitis. It seems as if our smoking habits, or lack of them, may play some role in predetermining the type of colitis we might experience. *Br Med J*, Vol. 289, #6450, p. 954, 1984.

DES:

The use of diethylstilbestrol (DES) during pregnancy is associated with the increased risk of vaginal and cervical carcinoma when the offspring reaches puberty. Studies have been conducted in mothers given this drug during pregnancy to determine if they were at greater risk of breast cancer. Although the incidence of breast cancer was higher in this group of women, no direct association could be made between DES administration and breast cancer. *N Engl J Med*, Vol. 311, #22, p. 1393, 1984.

INSULIN SECRETION:

Some problems have developed while studying insulin activity in plasma because insulin is rapidly cleared by the liver or binds to tissue receptors. Actual release of insulin by the pancreas may be more extensive than revealed by measuring insulin plasma activity. Investigators have found that Peptide C, a substance secreted in equimolar ratios along with insulin, does not undergo this rapid distribution or metabolism. The authors suggest that if an indicator of insulin secretion is required Peptide C, rather than insulin concentrations, would produce more reliable data. *J Clin Invest*, Vol. 74, #5, p. 1821, 1984.

PINDOLOL AND ATENOLOL:

Beta-adrenergic blockade is accomplished by oral administration of agents such as pindolol (Viskin) and atenolol (Tenormin). Pindolol is said to have partial agonist activity which will prevent the development of bradycardia. Investigators have used both drugs experimentally in patients with severe angina and have concluded that the partial agonist activity associated with some beta adrenergic blocking drugs may be a disadvantage to the anginal patient because of the chance that the drug might actually keep the heart rate at levels high enough to precipitate an anginal attack. *Br Med J*, Vol. 289, #6450, p. 951, 1984.

DILTIAZEM:

The calcium channel blockers inhibit the contraction of smooth muscle tissue by preventing the influx of calcium ions needed for activation of the actin/myosin complex. Diltiazem (Cardizem) was used as an antihypertensive agent in a double-blind study in patients with essential hypertension. Investigators concluded that diltiazem can be used effectively as an antihypertension agent in patients with mild to moderate essential hypertension. Clin Ther, Vol. 6, #6, p. 844, 1984.

PROSTATE CANCER:

Metastatic prostatic cancer has been treated with diethylstilbestrol to suppress symptoms of this disease. Side effects have been limiting so a search for safer, less toxic substances was started. It appears that a new gonadotropin-releasing hormone analog, leuprolide, provides the same benefit as does diethylstilbesterol without exerting serious toxicity. *N Engl J Med*, Vol. 311, #20, p. 1281, 1984.

ULTRASOUND:

Ultrasound techniques have been used for some time, but recent advances in this method of non-invasive imaging have led to improving information in two major areas of study. The modern ultrasound imaging allows for more accurate diagnosis and monitoring of fetal abnormalities and has greatly increased the ability of investigators to monitor normal fetal development. *Am Sci*, Vol. 72, #6, p. 608, 1984.

CIMETIDINE:

The action of cimetidine (Tagamet) on the microsomal metabolizing system of the liver is well documented. It was of some interest to see if this widely used agent might be capable of inhibiting the acetylation process which is responsible for the metabolic disposition of several drugs including dapsone, hydralazine, isoniazid, etc. Investigators have concluded that cimetidine does not interfere with the acetylation process. *Drug Metab Dispos*, Vol. 12, #6, p. 782, 1984.

INDECAINIDE:

Indecainide is an antiarrhythmic agent currently undergoing investigation to determine if it has characteristics which might favor it's use over other similar agents. It is useful against a wide variety of arrhythmias and can be used either intravenously or via oral routes. Preliminary information suggests that indecainide may lack the central nervous system stimulating activity which is characteristic of drugs with similar structure. If this observation holds true, the new drug might play a role in the treatment of arrhythmias in place of drugs which tend to produce unwanted central effects. *Drug Metab Dispos*, Vol. 12, #6, p. 683, 1984.

NEOMYCIN:

Neomycin has long been recognized as an agent capable of reducing the concentration of cholesterol in the plasma, but it has not been utilized much for this activity. A study conducted in 20 subjects for 9 months indicates that the drug can reduce the uptake of cholesterol significantly if it is ingested in doses of 1000 mg twice daily after the two largest meals of the day. The cost of this therapy is less than that of the bile sequesterants and is better tolerated. Ototoxicity and renal damage do not appear until daily doses approximate 12 to 14 grams/day, so this regimen is considered safe in patients with normal renal and hepatic function. *Clin Pharmacol Ther*, Vol. 36, #4, p. 555, 1984.

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The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Cromwell Bridge Road Beltway Exit No. 29. For further information contact President Frank Block (phone: 358-2743). This organization has several veteran pharmacists available for part-time employment.

Baltimore City College Alumni

The Baltimore City College Alumni Association is alive and well and working vigorously to support the old "Castle on the Hill." All B.C.C. Alumni are urged to support their old school with their membership. An application may be obtained by phoning 484-5262 evenings.

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July 4-11—American Association of Colleges of Pharmacy annual meeting, San Francisco, CA. July 31-Aug 4—American College of Apothecaries annual meeting, San Francisco, CA.

October 20-24—National Association of Retail Druggists annual meeting, New York, NY.

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Hydrochlortl	niazio	de :	25	mg
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.0120 per ml
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.0383 per capsule
.0505 per capsule
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THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

August, 1985 VOL. 61 NO. 8





103rd Annual Convention Coverage

OTC Oral Health Care Products

— J. Richard Wuest — Thomas A. Gossel

Abstracts

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET **BALTIMORE MARYLAND 21201** TELEPHONE 301/727-0746

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Guest Message

I appreciate the invitation as president of the Maryland Society of Hospital Pharmacists to address the membership of the Maryland Pharmaceutical Association.

The events of the past few years have offered a preview of the issues that will envelope the Maryland Society of Hospital Pharmacists during the next year and will undoubtedly influence the Maryland Pharmaceutical Association and the interaction of the two organizations.

The delivery of health care services has become unsettled in its identification and methodology. The emphasis toward an increased reliance on the patient's individual responsibility and the transfer of care to the home environment have changed the view of what constitutes health care.

These changes have influenced the realization that the goals and the philosophies of our organization will change in order to survive. Each component of the organization must be scrutinized: the structure, the value system, the decisions, and the direction.

The Maryland Society of Hospital Pharmacists is influenced by modernization in the form of mandatory continuing education requirements; transformation as the definition of active membership is modified to include any licensed pharmacist who support the philosophies of the American Society of Hospital Pharmacists.

The practice of a health care profession in the future will be altered substantially from its role today. The specific changes that will occur remain as areas of conjecture and debate. The profession and the Society specifically must move forward, actively, unhesitantly, embracing change as it occurs and to mold pharmacy to allow the practitioner to function as an integral part of the health care delivery system.

Both organizations are on the threshold of an era that will foster a positive relationship which encourages support and commitment of a common aim. Together we can share this year of opportunity for change.

Morrell C. Delcher, MBA

President, MSHP



Charles West, Executive Vice President of the National Association of Retail Druggists, delivered the featured address at the Annual Banquet.



The Board of Trustees are shown following the Banquet. They are (first row, left to right) Trustee Stan Brown, Trustee Norma Schapiro, Trustee llene Zuckerman, Trustee Harry Hamet, House Speaker Lee Ahlstrom, (second row) Honorary President Peter Lamy, Treasurer Nick Lykos, President-elect George Voxakis, House Vice Speaker Elwin Alpern, (third row) Board Chairman Ron Sanford, President Madeline Feinberg and Executive Director Dave Banta. Not Shown are: Vice President Jim TerBorg, Trustee Dennis Hager and Trustee Martin Mintz.



Frank Block (left) received the MPhA's Distinguished Achievement Award for his lifelong contributions to the Profession of Pharmacy in Maryland from MPhA President Ronald Sanford.

"Pride and The 103rd Annual



President Sanford cuts the ribbon opening the Exhibit Hall as members wait patiently to enter.



Thirty four exhibitors participated in this year's convention exhib program which featured a sweepstakes drawing for a televisio set.



Peter P. Lamy (left) receives the Honorary President's Award at the Convention Banquet from President Ronald Sanford.



Accomplishment' MPhA Convention

Photos Courtesy of Abe Bloom



Ray Langston (left) from the A. H. Robbins Company, presents the Bowl of Hygeia Award to Marvin Freedenberg (left) in recognition of his outstanding participation in Community service projects. Freedenberg was recently appointed to the Board of the American Cancer Society.



Two surprise Awards were delivered at the Convention. Here inthe coming President Madeline Feinberg receives a special award from Walter Wegline of the Warner Lambert Company in recognition of her work in the Elder Ed Program.



The other Surprise Award was the "Golden Shovel—Back to the Garden" Award given to retiring Treasurer Melvin Rubin (left) from President Ronald Sanford after Mel's many years of service to the Association as Treasurer following a term as President.

103rd MPhA Convention 1985 Resolutions Committee Report

by Elwin Alpern, Chairman

Resolution number One:

Whereas, Mandatory Continuing Education for Pharmacists will take effect on July 1st, 1986, and

Whereas, Pharmacists will most likely earn the majority of the thirty Continuing Education credits by attending Continuing Education Seminars, and

Whereas, Pharmacists may be required to pay registration fees for these courses and/or attend these courses on their own time.

Therefore, be it resolved that the Maryland Pharmaceutical Association recommends that employers consider providing financial reimbursement and/or compensation time for pharmacists to attend Continuing Education Seminars.

(Defeated)

Resolution number Two:

Whereas, the Maryland Pharmaceutical Association House of Delegates passes resolutions on a yearly basis at their Annual Convention.

Whereas, the resolutions are the main mechanism for the members of the Maryland Pharmaceutical Association to direct the operation of the Association,

Whereas, no formal mechanism now exists for the membership to be informed about the disposition of the resolution.

Therefore, be it resolved that the Maryland Pharmaceutical Association submit an oral and written report to the membership at the following annual meeting that states what steps the Association has taken to satisfy the intent of each of the resolutions, and

Therefore, be it resolved that this report be published in the *Maryland Pharmacist* as part of the convention report. (Passed)

Resolution number Three:

Whereas, the drug culture contributes to the degradation of our society; and

Whereas, the pharmacists in the state of Maryland have gone on record wishing to do everything in their power to eliminate the illicit use of drugs; and

Whereas, periodicals that glamorize the indiscriminate use of drugs, violate principles that are basic to pharmacy practice and contribute to increased illegal drug use;

Therefore be it resolved, that the Maryland Pharmaceutical Association discourage community pharmacies from

selling magazines and books that glamorize substance abuse:

And be it further resolved that the Association present a similar resolution to the House of Delegates of the American Pharmaceutical Association. (Defeated)

Resolution number Four:

Whereas, the professional services of a pharmacist are a vital and necessary part of any drug deliver system, and

Whereas, the dispensing of prescription drugs by physicians for profit is not in the best interest of the public health because it denies the patient the advantages of a personal consulting relationship with a pharmacist;

Therefore, be it resolved that any system which encourages physician dispensing of prescription drugs for profit is condemned as contrary to good personal and public health, and

Be it further resolved that the Maryland Pharmaceutical Association introduce resolutions to regulate those authorized prescribers who dispense prescription drugs for human consumption for profit. (Passed)

Resolution number Five:

Whereas, third party prescription drug plans have increasingly adopted provisions in their plans which deny patients the right of freedom of choice due to cost containment pressures, and

Whereas, there are many other cost containment options available to third party prescription drug plans which do not deny patients their right to freedom of choice of pharmacy providers;

Therefore, be it resolved that the Maryland Pharmaceutical Association conduct a statewide educational symposium for the administrators of health care plans to discuss health care cost containment strategies that emphasize freedom of choice. (Passed)





Speaker of the House of Delegates, Lee Ahlstrom (left) receives the Past Speaker's Award from President Ronald Sanford.

RESOLUTION UNDER NEW BUSINESS

Whereas, Pharmacists are individual health care providers and not "things" of Pharmacy; and

Whereas, the Maryland Pharmaceutical Association has been our organizational name for 103 years and we are still confused as being an association of drug manufacturers; and

Whereas, the word "Pharmaceutical" is both an adjective and noun and the word "Pharmacist" is only a noun; and

Whereas, a change of name of the Association to "Maryland Pharmacists Association" would reflect a more accurate representation of us as individuals rather than "things"

Therefore, be it resolved that the name of the Association be changed to "Maryland Pharmacists Association" and that the Officers and Board be instructed to take any necessary legal steps to complete this change of name. (Passed)

HOUSE MOTION

I move that the Maryland Pharmaceutical Association, n convention assembled, recognize the American Heart Association—Maryland Affiliate, for its progressive programs on behalf of the citizens of Maryland; especially its adoption of the University of Maryland's Pharmacy High Blood Pressure Program as a major portion of its Medical and Community Program. This recognition of the role of he Pharmacist in the treatment and control of High Blood Pressure is acknowledged and commended. (Passed)

SPEAKER OF THE HOUSE REPORT

by Lee Ahlstrom, Speaker of the House

It has been a distinct pleasure to serve as Speaker of the House this past year. I would like to take this opportunity to thank the officers, board members, staff of the Maryland Pharmaceutical Association, especially Executive Director David Banta for their help and support at the mid-year meeting and also at the convention here at Ocean City.

The mid-year meeting was held January 27, 1985 at the Annapolis Hilton. The program again featured an update on new drugs by Thomas Gossell and J. Richard Wuest, and also an extensive review of modern merchandising concepts by Jean Paul Gagnon, Professor of Pharmacy Practice at the University of North Carolina School of Pharmacy and current AACP President. Grady Dale, Assistant Dean at the University of Maryland School of Pharmacy, honored the sponsors and participants of the recruitment promotion sponsored by the University of Maryland School of Pharmacy. A short House of Delegates meeting followed, the highlight of which was the ratification of the nominations submitted for the vacant Board of Pharmacy Seat. Harry Hamet emerged as the first choice of the House of Delegates.

In closing, I would like to encourage any member who wishes attention focused on a particular issue to submit a resolution to the House of Delegates. The nature of these resolutions has changed dramatically in recent years. Where they were once used to thank the Mayor of Ocean City for his hospitality or WCAO for airing a radio program, now they serve as mandates for actions to the leadership on areas where change is needed. Recent examples are last years resolution favoring mandatory continuing education which passed the legislature in the last session, and the repeal of the price poster the previous year. I thank you for your continued support of the association and wish you prosperity and good health in the coming year.



Incoming President Madeline Feinberg receives the gavel of her office following installation by former Chairman of the Board, William Hill.



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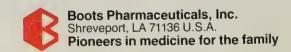
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EXECUTIVE DIRECTOR'S REPORT

David A. Banta, C.A.E.

This past year has been an exciting one for the leadership of the Maryland Pharmaceutical Association. Under the Presidency of Ronald Sanford, the Association was able to accomplish most of the objectives which we had set out for ourselves. Many of these accomplishments are recorded in other reports. However, I would like to highlight a few events which I consider to be especially significant.

I think it is again important that the Maryland Association and the Delaware Society of Pharmacists have joined together for our second joint convention. In another sign of inter-association cooperation, the Maryland Pharmaceutical Association has recently accepted an offer from the Mid Atlantic Food Dealers Association to provide a coupon redemption service to members and we expect the development of many more joint membership benefits. Maryland has increased its visibility on a national level. We participated in the USP Convention, the Southeast Regional States Conventions, APhA affiliated states Meetings, NARD buying group conference, NCSPAE Third Party conference, NACDS convention, An "American Druggist" meeting on cost containment, NARD legislative conference, and the Conventions of NARD and APhA. At the APhA Convention, the Maryland Delegation succeeded in passing a policy resolution on home health care under new business on the floor of the House of Delegates. The School of Pharmacy and the Association have become recognized on a national basis as leaders in issues of the elderly and health care.

This year's Convention is another in a series of successful Association meetings. The exhibit program, attendance and programming are stronger than ever. The Mid Year meeting was well-attended and drew good reviews. The Association sponsored trips to Paris and St. Maarten

were very successful.

Among issues that were addressed over the past year. the Association worked to convince Blue Cross and Blue Shield that a mail order prescription drug program would not be in the best interests of the public health, the company or pharmacy providers. We have apparently succeeded. The Association has continued its public education campaign regarding the disadvantages to the public from mail order prescription drug plans. In another successful campaign, the Association waged a battle to preserve the principle of freedom of choice for HMO subscribers. Legislative initiatives combined with face to face negotiations have resulted in an open pharmacy network for all Maryland HMOs to date.

Not all of the news was good, however. After a two and a half year compromise process, the Medicaid program enacted a mandatory generic drug program over the obections of the Association. It includes no reimbursement o pharmacists for the overhead costs associated with proiding generic drugs to Medicaid recipients and there have peen no official indications that these and other increased costs of participating in the program will be met through a future Medicaid fee increase. After well over a year, the Medicaid program has not accepted the Association's Drug Utilization Review proposal which we believe could ave the program more money than any generic drug pro-



The MPhA filed a "friend of the Court" petitition with the U.S. Supreme Court in the Portland Retail Drug case to determine if non-profit HMO's could use manufacture's preferential prices in competition in the retail market. Unfortunately, the Supreme Court refused to hear the case and let stand a lower court decision which appears to be

very damaging to community retail pharmacy.

The Association is facing a number of current issues which I am certain will occupy our time and resources in the coming year. The emergence of Physician Dispensing programs, in some cases sponsored by pharmacists, is a growing concern of the Association's. The MPhA has formed a Task Force committee at the Board level to investigate the feasibility and options available in forming a sponsored buying cooperative and pharmacy PPO. The Association hosted the first Maryland conference between the MPhA and the Maryland Association of Chain Drug Stores to establish a working dialogue between the two groups. Manpower shortages, morale, economic issues, public image and inter-professional relations are all issues which will continue to be addressed.

I am pleased that the Association continues to grow stronger each year in terms of membership and assets. This is reflected in other reports to the membership. We have made substantial improvements in the Kelly Building in the recent year. These include new carpeting, painting and other improvements. Now we await the construction of the new Shock Trauma Building behind the Kelly Building before we consider additional reconfigurations

of the Building.

It was a most interesting and successful Legislative Session. The Association took the policy mandate represented by the passage of a resolution at last year's Convention and succeeded in passing a mandatory continuing education bill for pharmacist relicensure. It will take effect in 1986. Working with a coalition of other health care provider groups, the Association successfully worked for passage of legislation which will regulate PPO's. The Association defeated legislation mandating triplicate prescription forms for CDS drugs, a bill which would require the listing of inactive ingredients on the prescription label, and a bill which would have mandated the listing of the date on the label beyond which the drug had lost potency.

It has been a very rewarding and fulfilling year for me personally. I finished my year as President of the Maryland Society of Association Executives and now serve as Chairman of the Board of that organization. Also, I completed my term as Chairman of the Board of the National Council of State Pharmaceutical Association Executives. I sincerely appreciate the support and hard work of the Officers, Trustees, Committee Chairmen and the membership. This Association is capable of growing and continuing its tradition of innovation and progress. Thank you

for allowing me to contribute to these efforts.

LEGISLATIVE COMMITTEE REPORT

Milton Sappe, Chairman

Not a dramatic or earth-shaking session for the Maryland Pharmaceutical Association, yet overall a very successful one.

At last summer's House of Delegates meeting, a resolution was passed instructing your Association to go before the legislature for the purpose of seeking a continuing education bill. This was successfully done. This year we were at the right place at the right time. As many of you know, this bill was introduced many times before. Persistence pays off. This bill will be implemented by the Board of Pharmacy by 1986 after hearing all interested parties.

At this year's session your Association finally attracted the attention of the HMO's and the Insurance Commissioner with it's introduction of the HMO Freedom of Choice Bill sponsored by Senator Steinberg and many others. While we failed to get it passed, it is still alive. The bill has been submitted to summer study and will be introduced next year if needed.

An observation: Bills with some merit, and even those with little, will, with persistence and diligence eventually find favorable conditions to be passed. It took us several attempts to repeal the infamous price poster bill and this year continuing education passed after several tries. Maybe next year we will succeed at placing third party payees under supervision of the insurance commission.

Following are some of the bills which were closely

monitored by the MPhA:

SB 710/HB 1572 (passed) Authorizes the Board of Pharmacy to waive certain requirements for pharmacies engaged in Pharmaceutical specialties.

SB 633/HB 1567 (passed) Allows the Board to maintain a record of the Pharmacists place of business or home

address.

SB 754 (passed) Mandatory Continuing Education requirement for relicensure to take effect July 1, 1986

HB 669/SB 722 (failed) Would have allowed any pharmacy which is willing to meet the requirements of an HMO to participate as a provider for that HMO.

HB 131 (failed) Would have required the date on the label beyond which a prescription drug loses its potency.

SB 298 (passed) A health care coalition bill to regulate PPO's which guarantees freedom of choice at a reduced reimbursement rate.

HB 1515 (failed) Would require triplicate prescription form for CDS drugs. Defeated on a close vote in Committee.

HB 1267 (failed) Would have required that the prescription label list all inactive ingredients in any prescription drug

HB 1487 (failed) Would mandate patient package in-

serts.

HB 959 (failed) Would mandate the use of all generics

in the Medicaid program.

There were over 3,000 bills introduced in the last General Session. Many of these dealt with Health Care issues. If you have any questions regarding a bill that has not been listed, contact the office.



Don Fedder (left) Chairman of the Maryland High Blood Pressure Commission, welcomes Convention Committee Chairman Elwin Alpern to the Exhibit area. The Commission was praised in a special House Motion (See page 7).

TRAVEL AND **CONVENTION REPORT**

Elwin Alpern, Chairman

Our 1984 Convention at the Carousel in Ocean City had an attendance of 300 people. There were 29 exhibitors in 1984 with fees totaling \$6,465.00 and contributions of \$4,200.00. The registration fees accounted for \$10,873.00. The net profit was \$7,934.79. It is the continued thinking that as long as Ocean City is so well attended we should continue to have our convention there.

In January, 1984, we offered a trip to Mexico and had an attendance of 140 people which netted the Association

\$2,100.00.

Our trip to Paris in October 1984 was a huge success. A total of 264 people attended and the profit realized was \$4,035.00. One of the most profitable trips we sponsored by far.

In January 1985 a trip to St. Maarten was offered and 63 people attended netting our Association \$945.00.

The total amount of profitable funds collected from June 1984 thru May 1985 by the Travel and Convention Committee efforts was \$15,059.79. This Committee welcomes any and all suggestions for the future.

Thank you.

INDUSTRY RELATIONS **COMMITTEE REPORT**

Mark Golibart, Chairman

The Industry Relations Committee of the Maryland Pharmaceutical Association met to discuss a number of important issues.

The Committee was concerned that certain OTC products do not list active ingredients of the product on the label. A member had complained that when OTC products are reformulated, the manufacturer fails to notify the Pharmacists about the changes. The Committee communi cated with the Proprietary Association on this problem.

sioner of the Food and Drug Administration, suggesting that he use his influence to suggest that Federal Government employees be encouraged to carry personal patient medication histories as part of a larger campaign to spread their use in the United States.

The Committee has also been following the on-going negotiations between the Association and the Medicaid Program regarding the Generic Drug Price Regulations

and the Drug Utilization Review Proposal (DUR).

The Committee continued its on-going ombudsman activity with regard to return goods policies. On behalf of the Committee, staff made several inquiries throughout the year to help pharmacists establish constructive dialogue and productive results from manufacturers on this issue.

The Committee continues to be open to suggestions from the membership and openly solicits, at this time, your suggestions concerning issues involving Pharmacy-Industry relations. I appreciate the work of the Committee members and the special contributions of the office staff to the work of the Committee.



Tom LaMartina, President of the Student APhA Chapter, delivers the annual report of the student group.

SAPhA REPORT

by
Tom LaMartina, SAPhA President

SAPhA has spent much time this year straightening out administrative problems and becoming acquainted with The National Office. The San Antonio Convention was very beneficial this year. Twelve students represented Maryland. The lectures, seminars, and the student House of Representatives was an educating and pleasant experience. In the SAPhA House of Representatives, Maryland was out vote—54 in Favor to our 1 vote Against the motion to support the licensing of Drug Technicians. Maryland discussed the possible future consequences—especially due to mail order pharmacies, and other future legislation. Also, many new ideas from other chapters were discussed and will be incorporated into our SAPhA group to achieve a stronger organization.

The annual coffeehouse was a success. Many students and faculty display their talents by performing in the talent show which helped raise money for SAPhA. Everyone in-

volved had a good time.

Next year Maryland SAPhA will become active on both ocal and national levels and will work closing with the other organizations at Maryland Pharmacy School.

THIRD PARTY COMMITTEE REPORT

by George Voxakis, Chairman

Serving on the Third Party Committee, more than anything else, fills one with a sense of frustration. It is difficult to accomplish much when the negotiations are almost completely one-side. Why should a Third Party Administrator allow any concessions or even negotiate with us when he can go "down the street" and find someone willing to fill his needs with almost no compensation? As a result, those who sit in board rooms—not practicing pharmacists—are determining how our profession is compensated.

Nevertheless, we can point to two accomplishments this year, with the promise of more in the future. First, working in conjunction with the Legislative Committee, we were successful in acquiring the right of all pharmacists, who so desire, to fill prescriptions written by various

HMO's. Heretofore, this right was denied us.

Secondly, we have laid the groundwork to cooperate in public relations campaigns on the Freedom of Choice issue—that is, the right of patients or subscribers to choose their own physician, pharmacist, etc. Hopefully, this will proceed and include the medical, dental, pharmaceutical, and optometric associations. Our goal is to educate the public not to give up the freedom of choice they now enjoy.

Despite the obstacles we face, we can and will make

progress as long as pharmacists stand together.

MEMBERSHIP COMPARISON REPORT

by Frank Blatt, Chairman

		6/14/83	6/14/8	34 6/14/85
Total Members to Date: New Members to Date:		938 104	1007	
Comparison: 1984 to Members to Date: New Members to da				+ 16 - 17
	6/14/83	6/14/84	6/14/85	Comparison
Breakdown:				
Owner-Manager	185	193	210	+ 17
Non-owner	422	451	451	
Pledge—1st Year	56	61	52	-9
—2nd Year	32	30	40	-10
Hospital	33	27	33	+6
Graduate	2	6	9	+3
Retired	89	116	113	-3
Non-Resident	80	85	82	-3
Joint	7	7	7	
Associate	32	31	29	-2
Comparison:	938	1007	1023	+ 16

I would like to extend my fullest appreciation to the Membership Committee, David Banta, and Beverly Litsinger for their time and efforts this year. Statistics show that we are making steady progress in membership when compared to previous years. I would like to invite new volunteers to be a part of this committee. A few hours a year spent in any committee work really gives on a sense of great accomplishment.

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PROFESSIONAL AFFAIRS COMMITTEE REPORT TASK FORCE ON HOME HEALTH CARE

by Madeline Feinberg, Chairperson

Activities of the Professional Affairs Committee were focused again this year through the Task Force on Home Health Care. Individual members of the Task Force represented Maryland pharmacy at the state and national levels on issues pertaining to home health care.

At the state level: Task force members were invited to comment on proposed regulations governing pharmacies which provide sterile parenteral products to patients at home. These regulations are in the approval process at

this time.

The regional meeting of the National Association of Boards of Pharmacy and the American Association of Colleges of Pharmacy was held in Baltimore this year. Presentations by several task force members on perspectives and initiatives within pharmacy in the home health care

setting were given.

Hearings held in January 1985 by the Department of Health and Mental Hygiene regarding proposed changes in covered services for Medical Assistance recipients receiving home health care presented the opportunity for the Association to raise issues regarding the total absence of pharmacist involvement in patient management in the home. Current regulations provide for reimbursement for drug regimen monitoring by a registered nurse or by a home health aide acting under the supervision of the registered nurse. Task Force members testified for the need to provide for direct pharmacist input in management of drug therapy for the home health care patient. Supporting testimony for this position was given by the Baltimore Visiting Nurse Association, a licensed home health agency. (copies of testimony available through Task Force) Not surprisingly, state officials of DHMH point to federal guidelines (Medicare), noting the absence of provision for direct reimbursement for pharmacist consultant services, which indeed highlights the need for pharmacy to work at the national level to change current regulations.

Educating the regulators about the changing concepts of pharmacy practice has been identified as a goal of the Task Force. To implement this we met with the chief of the Division of Licensing and Certification (DHMH) to explore opportunities of meeting with his staff to present pharmacy issues. This Division is responsible for licensing of nursing homes, home health agencies, domiciliary care units and other institutions within the state. Indeed, surveyors frequently encounter drug-related problems within these settings, particularly where pharmacy services are not mandated. (e.g. domiciliary care units). It is the intention of Task Force members to present the scope of services which pharmacy can provide to these institutions, as well as to learn from this group where the need might exist for pharmacists participation. We received an enthusiastic response and we are currently planning bimonthly

luncheon presentations for the division staff.

Finally, at the state level, we met with the Executive Director and the President of the Maryland Association of Home Health Agencies (MAHHA) on an informal basis to explore issues of common concern. While we feel strongly for the need to include pharmacist services in the interdisciplinary care of the home-bound patient, MAHHA



Madeline Feinberg received the traditional captain's hat signaling the change in leadership from out-going President Ronald Sanford. Feinberg, among other things, chaired the Professional Affairs Committee and Task Force on Home Health Care.

voiced concern as to the duplication of services, particularly with regard to the patient receiving parenteral therapies in the home. We offered to make a presentation to the MAHHA Board of Directors and wait their response. An article describing the role the consultant pharmacists within a home health care agency was printed in the February issue of the MAHHA newsletter.

At the National level: Feinberg has been appointed Chairman-Elect of the newly created Section on Home Health Care within the APhA Academy of Pharmacy Prac-

tice.

Most notably, a resolution supporting the role of the consulting pharmacist in home health care was developed by Dr. Peter Lamy of the Center for the Study of Pharmacy and Therapeutics for the Elderly, and cosponsored by the MPhA at the APhA House of Delegates annual meeting in San Antonio in Feb. 1985. The resolution was passed as follows:

New Business

1. Pharmacists and Home Health Care. Motion: 1. APhA supports establishment of pharmacist consulting

services for Home Care.

2. Medicaid and other third-party programs should recognize the consulting role of the pharmacist in reducing the misuse of drugs and maximizing their therapeutic effectiveness through fair and equitable reimbursement for consulting functions which is not tied to the provision of medications.

3. Medicaid and other third-party programs also should reimburse pharmacists for innovative packaging and services that will minimize drug defaulting, increase the opportunity for audit and drug use review and meet better the informational need of the elderly and the care-

giver.

Also, very importantly on the national level, members of the MPhA Task Force were invited to attend the American Society of Consulting Pharmacists' Council of Past President meeting in January 1985 to offer some perspectives on the need for the ASCP to strongly endorse the consulting pharmacists concept of home care. We are pleased to report that Council agreed with our viewpoint, and recommended to the ASCP Board of Directors that this issue be pursued at the national level. ASCP legal counsel has drafted changes in regulation to this end.

In conclusion, the Chairman wishes to take this opportunity to thank the individual members of this Task Force for their time and commitment in representing pharmacy and MPhA in the rapidly growing and changing field of home health care. This year's activities represents the

work of many dedicated individuals.

Task Force Committee Members:

Madeline Feinberg, Chairperson

Lee Ahlstrom Melvin Chaiet Steven Cohen Donald Fedder Jerome L. Fine William C. Hawk Peter Lamy John McGraff Debbie Nacardo Marvin Oed Paul Pitoke Roslyn Scheer Ralph Small Paul Vitale Ilene Zuckerman

PHARMACIST REHABILITATION COMMITTEE REPORT

by Harry Fink, Jr., Chairman Tony Tommasello, Chairman

The Committee is almost two years old and has referred approximately 20 pharmacists for treatment. We have grown faster than we anticipated and the workload is becoming more demanding than just a volunteer status can handle. The majority of the pharmacists are doing well and getting prepared to enter practice again. What the Committee is asking of our colleagues is that you send your name to MPhA office or give it to one of our representatives here if you are interested in hiring one of the recovered pharmacists. We believe you will find an honest and sincere employee who has been through a rehabilitation process that is very successful. These pharmacists are dedicated because they know they have to do well and they have already sacrificed a lot to get where they are now. Please do not let these men and woman down, their illness is no different medically than any other illness. It is treatable with the proper professional help which is why we are here. We are all in a helping profession so let's demonstrate some compassion and show our colleagues that we really do care.

Business:

Our Committee needs volunteers because of the increasing demand for time. We meet one Wednesday every month for two hours which is really not enough time. The Committee is already overburdened with work and our budget is zero. The Committee would like financial support from MPhA for educational seminars in treating drug addictions, travel expenses, printed material and the possibility of hiring a part time secretary to handle the workload. Anyone wishing to make a contribution please send it to the MPhA office and mark it for the Pharmacist Rehabilitation Committee. We need your help because chemical impairment is a very real manifestation due to the stresses of our profession. We are successful, but only because of the time and effort contributed by the following:

Gil Cohen John Davis Harry Finke, Jr. Bernard Lachman May Sure Long John McGrath Berry Means Allan Novak Mike Sohmer Tony Tommasello Charles Whitfield

I would like to again extend my appreciation to the above men and women for their dedication and valuable donated time. If it was not for them there would be a lot of pharmacists in some sort of medical or legal trouble. I would also like to thank the State Board of Pharmacy for their cooperation, support and legal guidance. Remember

the one binding factor which gives this Committee cohesion and strength is the confidentiality with which we conduct our business.

CONTINUING EDUCATION COORDINATING COUNCIL REPORT

by David A. Banta

The Continuing Education Coordinating Council has again experienced a productive year and is a model of cooperative effort among the three organizations that participate. The MPhA, the MSHP and the School each have representatives on the Council and over the past several years the Council has succeeded in developing a high standard for programming. As in the past, the Council solicits for volunteers who are interested in the process of providing quality educational experiences for Maryland Pharmacists to assist the Council in this important work. Please contact me if you are interested in assiting.

Last season's programs included successful day long seminars on the subjects of "New Concepts in Psychiatry," "Drug Abuse," and the "Pharmacist's Role in Eye Care." Unfortunately, the Henry Seidman Seminar on "The Pharmacist and Ostomy Patients" was cancelled due to poor pre-program registration. It will be rescheduled as the first program in the Fall; probably in September, 1985. The traveling "Road Show" on new drugs was again made available to local associations to assist them with their program needs. The Council met throughout the year to review program plans with the various Chairmen who have major responsibility for organizing these continuing education programs.

As you know, the Council has received approval from the American Council on Pharmaceutical Education (ACPE) as an approved provider of Continuing Education programming. The Council is now offering programs with ACPE approval. In addition, the Council has developed cosponsorship guidelines whereby other organizations might produce C.E. programs but offer ACPE credit

through the Council.

The Council is working to gain a special non-profit tax status to help lower the cost of state-wide mailings by taking advantage of lower postal rates. The Council has again initiated an elaborate planning process for the coming season and has begun the task of raising necessary financial support for these programs. The Subcommittee on planning has presented a list of proposed programs for the 1984-85 season. In addition to the "Ostomy" program already mentioned, the Council is planning a program on "Infectious Diseases" for Sunday, November 11, 1985. Mark your calendars now. In the Spring of 1986, the Council will present programs on the topics of "Family Planning" and "Diabetes." Additional information on the new C.E. season will be available in the Fall. The Council anticipates renewed interest in Continuing Education programming due to the passage of the Mandatory Continuing Education bill in the last session of the legislature.

In addition, the Council will continue the work of the "Road Show." Selection of program topics is based, in part, on input from pharmacists who attend programming and participate in the Council's evaluation process.

I would like to thank all of the volunteers who have served on the Council, its subcommittees and as program chairman, for all of their hard work in developing and executing these programs. Thank you.

NECROLOGY REPORT

Deceased Alumni, Since June 1984 University of Maryland Pharmacy Alumni

Name	Class
Bishop, Davis M.	1952
Brodie, Stanley	1951
Geesay, Alton L.	1930
Leon Goodman	1941
Kern, Louis R. Jr.	1962
Kronthal, Jacob	1924
Lauten, Antoinette M.	1959
Lightner, Earl H. *	1916
Patton, Michael	1977
Pross, Ferdinand	1914
Santoni, Daniel A.	1933
Schapiro, Abraham	1930
Serpick, Jacob	1925
Siegel, Harold	1941
Stacy, Theodore, Jr.	1923
Stichman, Solomon	1928
Stiffman, George J.	1931
Tucker, Alexander	1934
Markin, Samuel	1933

TRIPARTITE COMMITTEE REPORT

MEMBERS

Estelle Cohen—Maryland Board of Pharmacy
Len DeMino—Maryland Board of Pharmacy
David A. Banta—Maryland Pharmaceutical Association
Lee Ahlstrom—Maryland Pharmaceutical Association
Melvin Rubin—Maryland Pharmaceutical Association
Harry Hamet—Maryland Society of Hospital Pharmacists
Barry Means—Maryland Society of Hospital Pharmacists
Ralph Shangraw—University of Maryland School of Pharmacy

Frank Palumbo—University of Maryland School of Pharmacy

Robert Kerr—University of Maryland School of Pharmacy

The TriPartite Committee met several times during the year and continues to act as a forum for discussion of issues which are then reported back to the organizations participating in the Committee. Among other issues discussed were:

1. Members discussed the need to continue the Tri-Partite Committee following a meeting where only two members participated. It was concluded that there continues to be a need for the Committee.

2. The University of Maryland's task force had undertaken an extensive review of the PharmD. Program which

was recently completed.

3. The School of Pharmacy underwent an accreditation process by the American Council on Pharmaceutical Education in January, 1985.

4. There was considerable discussion regarding the impact of the passage of the Mandatory Continuing Education Bill

5. Freedom of Choice for patients participating in HMO's led to the introduction of legislation on the subject.

6. The MPhA has launched a public education campaign advising consumers of the advantages of commu-

nity pharmacy service as compared to mail order prescription drug plans.

7. The Board is still working on Hospital Pharmacy Regulations. There was favorable comment on the District II meeting. The Parenteral Drug guidelines have been completed.

8. There was discussion about Physician dispensing systems and how they can be regulated to protect the

public health.

9. Current legislative matters were discussed.

Having merely touched on some of the issues under discussion at the Tripartite Committee meetings, we invite any queries you may have on our work, any suggestion you may have on matters of mutual concern.

Marvin Freedenberg, P.D. Elected to American Cancer Society's National Board of Directors

Marvin Freedenberg, P.D., of Silver Spring, Maryland, has been elected to the National Board of Directors of the American Cancer Society.

Mr. Freedenberg is President of Drug Lane Pharmacy in Hyattsville, Maryland, and is an active American Cancer Society volunteer at the state and local levels. As Past Chairman of the Board of the Society's Maryland Division, he is currently Chairman of the Division Survey and By-Laws Committees and is a member of the Division Executive Committee and Board of Directors, as well as the Service and Rehabilitation, Public Issues, Hope Lodge, Research, Personnel and Professors of Oncology Committees. Mr. Freedenberg will be the Division Public Issues Committee Chairman for 1985–87.

At the Montgomery County Unit level of the American Cancer Society, Mr. Freedenberg is a member of the Board of Directors and the Service and Rehabilitation and Professional Education Committees. He is also Past President of the Unit Board of Directors.

In addition to his volunteer work with the American Cancer Society, Mr. Freedenberg is active in a number of professional organizations, including the American Pharmaceutical Association, Maryland Pharmaceutical Association and special programs at the University of Maryland School of Pharmacy.

Freedenberg received the 1985 Bowl of Hygeia Award at the Annual Banquet. See picture on page 5.





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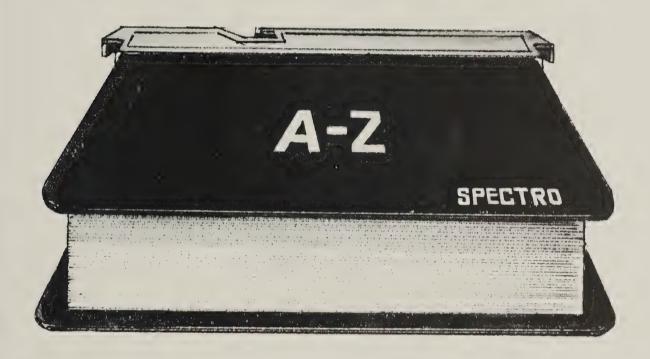
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VOL. II, NO. €

Objectives

At the completion of this lesson, the successful participant will be able to:

- recognize safe and effective OTC agents for treating minor mouth disorders;
- 2. identify the pharmacological action of these agents;
- 3. explain the proper technique for applying these products.

This is the second lesson in a three-part series on OTC remedies for oral discomfort and health. In the first article, the agents used for relief of oral discomfort were discussed. You may want to refer to the Glossary of Oral Health Care Terms included in that article.

This lesson will review drugs used for oral health care. They include the analgesics/anesthetics, antimicrobial agents, astringents, debriding agents, decongestants, demulcents, and expectorants.

Although there are some similarities among the drugs covered in these two lessons, the two categories of ingredients were reviewed separately by the FDA OTC panel.

Oral Bacteria

Bacteria surround us in our environment. Some of them reside in the alimentary canal. These are involved in many beneficial functions including digestion, vitamin production, and maintenance of a healthy flora. Nonpathogenic organisms have free entry into and out of the mouth, nasopharynx, and throat. They help prevent their pathogenic cousins from gaining a foothold there and overgrowing to cause disease.

The mouth possesses several physiological mechanisms to maintain a proper balance of bacteria and, therefore, a healthy state. It does this without mouthwashes, gargles, or the various "twice a day — once for me and once for you" products so frequently seen in television adver-

tising. Those that do not contain therapeutically active ingredien are considered by FDA to be cosme ics rather than drugs. As long as the manufacturers do not make specific drug-related claims, the cosmet products are not subject to the regulations explained in this lesson.

Many different glands moiste and clean the mouth's mucous mer branes and teeth, and possibly i hibit excessive bacterial growt These include the salivary, muco (secreting viscous materials), and s rous (secreting thin, watery fluid

glands.

There is little evidence to pro that oral health care products provent the development of any diseas or maintain a "healthy" state in of erwise well persons. However, in the presence of fever, and as a result the atropine-like side effects of sor drugs, oral secretions can be a creased, organic material may accompliate and decompose, and bacter can overgrow. Inflammations, ulcations, sore throat, mouth discomfund pain, and foul breath can result and may require some type of of health care product

Pain Receptors

Oral mucous membranes contsensory receptors for cold, paperessure, touch, warmth, and intongue, specialized receptors taste. Pain receptors will be empsized in this article because oral comfort and pain can be effectivalleviated by topical analgesics anesthetics. For example, local arthetics readily penetrate the mucmembranes of the mouth and inhthe passage of pain impulses to brain.

While systemic analgesics will be discussed in this lesson, it sho be kept in mind that oral pain also be relieved by raising the pattern of the psychol cal response to it. Aspirin and ac minophen can be recommended temporary relief of minor irritation

Advising Consumers on OTC Oral Health Care Products

by J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

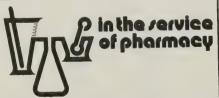
and

Thomas A. Gossel, R.Ph., Ph.D. Professor of Pharmacology and Toxicology Ohio Northern University Ada, OH

Goals

The goals of this lesson are to:

- discuss the pharmacology of drugs used to treat minor oral health disorders;
- 2. explain how to advise patients on their use.



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

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pain, sore throat and sore mouth. Eiher analgesic may be just as effecive, or more effective in some paients, as the topical anesthetics.

Sore throat may be described as ourning, discomfort or pain, or as a 'scratchy'' feeling, especially when wallowing. It is considered to be elf-treatable if it results from a comnon cold, minor irritation or trauma. However, lingering, persistent, or seere sore throat can also signal a nore serious disease state. Diseases or which sore throat is a symptom re listed in Table 1.

TABLE 1 Representative Diseases for Which Sore Throat is a Symptom

granulocytosis plastic anemia austic chemical poisoning hicken pox iphtheria preign substance reactions fluenza eukemia easles oniliasis (Thrush) ral gonorrhea neumonia oliomyelitis neumatic fever carlet fever nallpox philis nsillitis ncent's angina

When the regulation is finalized, e following warning statement will required to appear on all OTC oral

alth care products:

Severe or persistent sore throat or sore throat accompanied by fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor. Discontinue use and consult a doctor if irritation persists or increases or a rash appears on the skin.

Sore mouth may also be a sympn of some other disorder. There many causes of sore mouth inding burns, cancer, infections, tabolic disorders, systemic dise, and trauma — especially from properly fitted dentures. As with e throat, only a very few causes self-treatable. Also, the mouth its own efficient mechanisms for

healing minor sores without the aid of OTC products.

Nonetheless, oral health care products do play a beneficial role in alleviating pain of mild, benign, short-lived mouth sores. Local anesthetics (and systemic analgesics) can alleviate mouth pain or discomfort, and debriding agents can facilitate removal of exudate and debris from mouth sores. Astringents and demulcents can relieve discomfort, or form a protective covering over mouth sores preventing entry of irritating substances. These agents will now be discussed.

Anesthetics/Analgesics

Anesthetics/analgesics for oral health care are categorized into two groups: the "caine-type" anesthetics and the alcohol or hydroxyl compounds. The "caine-type" anesthetics penetrate into the oral mucosal membranes and block the pain receptors. The alcohol or hydroxyl compounds have various actions, one of which is to stimulate receptors other than those for pain - most specifically, the cold receptors. These agents may also depress the nerves or merely substitute the sensation of cold for pain.

In either instance, when an agent blocks the perception of pain only, it is officially referred to as an analgesic. When a drug also blocks cold, pressure, touch, and warmth (thereby inducing numbness), it is called an anesthetic. Since most of the agents that are effective in alleviating oral pain and discomfort produce both of these actions, depending on their concentrations within the epithelial tissue, we will refer to them from this point forward simply as local anesthetics.

It is hypothesized that the "cainetype" anesthetics change the pore size of neurons and, therefore, distort the channels for passage of sodium ions into the axon. This stabilizes the membrane of the nerve fiber in such a way that impulses generated cannot pass by and gain entry into the CNS. This action is reversible and dissipates as the anesthetic is metabolized and carried away from its site of local application.

Another agent that does not fall into either of the above groups is aspirin. Aspirin has elicited controversy within the OTC advisory panels.

The panel reviewing fever blister remedies concluded that aspirin may cause ulceration of the oral mucosa, and, therefore, should not be applied topically to the mouth. The panel reviewing OTC systemic analgesics stated that aspirin in chewing gum formulations may irritate and damage oral mucosa, and may be unsafe if the tissue is highly inflamed or abraded. That panel concluded that the topical use of aspirin for sore throat has not been adequately tested, and deferred all decisions to the Advisory Panel on OTC Oral Health Care Drugs.

The majority of the latter panel ruled that aspirin is a safe and effective analgesic for topical use on mucous membranes of the mouth and throat when used properly. The word majority is mentioned because several of the panel's members issued a minority report. The opinion of the minority was that aspirin does not exert a topical anesthetic effect, does not block transmission of nerve impulses, and, therefore, has no known anesthetic action on mucous membranes. These panel members further stated that gargling with aspirin solution produces irritation and burning instead of a numbness effect. It was the consensus of the minority that the topical use of aspirin in any form is unwarranted and unjustified, especially since safer and more effective agents are available.

The majority and, therefore, the official monograph opinion was that aspirin is unsafe for topical application to the oral mucosa after oral surgery, when the mucous membranes are highly inflamed or abraded, when there are ulcerations present, or when the person is taking oral anticoagulants. Otherwise the panel believed it to be safe and effective. It concluded that aspirin has a local analgesic action both from a peripheral effect and a systemic effect from absorbed aspirin. The proposed mechanism of action is that it blocks the chemoreceptors that mediate pain and inhibits prostaglandin synthesis. This reduces inflammation and removes one of the causes of pain. The majority view was that 130 to 500 mg of aspirin incorporated in a chewing gum base, to be chewed every four hours when needed, is safe and effective for OTC marketing. The panel recommended that several warnings appear on the labels of aspirin used for oral health related care. These are listed in Table 2.

TABLE 2 Suggested Warnings for Labeling of Oral Health Care Analgesics Containing Aspirin*

- Do not use if you are sensitive or allergic to aspirin.
- Do not use if you have a bleeding problem or if you are taking an anticoagulant drug.
- Do not use without a physician's or dentist's advice, if your mouth is highly irritated or ulcerated.
- Do not use after surgery on the mouth or throat.
- Provide good fluid intake when aspirin or aspirin-containing preparations are used.

*as determined by an FDA advisory panel

Benzocaine and dyclonine are two members of the "caine-type" local anesthetics that have been used for years for treating all types of topical pain. The panel approved benzocaine in a 5 to 20% gel or spray, and in a 0.05 to 0.1% strength for lozenge formulation. Dyclonine was accepted in concentrations of 0.05 to 0.1% for rinse, gargle, spray and lozenge dosage forms.

Representatives of the alcohol/hydroxyl-type topical anesthetics and concentrations that were approved are: benzyl alcohol, 0.05 to 0.1%; menthol, 0.04 to 2%; and salicyl alcohol, 1 to 6%. Phenol, its sodium salt, and its derivative hexylresorcinol were also accepted. The respective strengths are 0.5 to 1.5% for phenol and phenolate sodium, and 0.05 to 0.1% for hexylresorcinol. Available dosage forms include gargles, mouthwashes, rinses, sprays and lozenges.

Camphor and cresol were ruled to be neither safe nor effective because of lack of supporting evidence. Also, reports show that they may excessively irritate mucous membranes and are possibly absorbed in sufficient quantities to cause systemic effects. Dibucaine, lidocaine, and tetracaine were tabbed as effective, but unsafe for oral use. In the panel's opinion, they can be absorbed in sufficient quantities to be systemically toxic.

Eucalyptol, methyl salicylate and thymol were placed in the "needs more study" category. Even though they have characteristic "medicinal" odors, evidence that they actually exert a pharmacologically significant anesthetic effect on the oral mucosa is lacking. Other panels have also rejected their uses except as flavoring agents.

Antimicrobials

The antimicrobials have several mechanisms of action. Alcohol, phenol and salts of aluminum, mercury and zinc coagulate or denature protein within the protoplasm of susceptible organisms, and kill them. Surfactants such as the quaternary ammonium compounds affect the membrane surface tension of susceptible organisms and allow the escape of cellular content. The exact mechanism for this action is unknown, but it is thought to result from a combination of any of the following: disrupting of the cell membrane, dissolving the protective lipid film around the organism, denaturing cellular protein in the membrane, inactivating certain enzymes within the cell, or interfering with enzyme systems in the transport mechanism across cell membranes. Still other antimicrobials (e.g., hydrogen peroxide, carbamide peroxide) exert their mechanism of action by oxidizing and killing organisms.

A great deal of controversy surrounds the use of "antiseptic" solutions in the mouth. Some hold that the dynamic nature of a contaminated wound overwhelms the action of antiseptics and renders them useless. Others feel that antiseptics harm both microorganisms and human cells, and that the risks outweigh the benefits. More importantly, the introduction of antibiotics and chemotherapeutic agents specific for these organisms, without harming human cells, should have relegated antimicrobials such as boric acid and camphor into oblivion. Those who advocate the removal of antimicrobials for oral health care have listed their reasons in Table 3.

In spite of the above opinions, the general public and even health professionals are still convinced that the topical use of antiseptics will relieve symptoms of infection and accelerate healing. Documentation that

TABLE 3

Proposed Reasons Why Antimicrobials Are Not Appropriate for OTC Oral Health Care Use*

- Consumers cannot identify causative organisms
- Consumers cannot determine agent of choice
- Action is too superficial and does not penetrate down to the deep-seated organisms
- Nonpathogenic organisms are killed, therefore disturbing normal flora and possibly allowing overgrowth of pathogens
- Rapidly diluted and carried off by saliva and other secretions
- Resistant strains may develop
- Nullify the action of immune systems in the mouth
- No clinical trials have demonstrated that antimicrobials are safe or effectiv for this use
- Toxicity studies on long-term use are not available
- *as determined by an FDA advisory panel

these agents actually exert a beneficial antimicrobial action is lacking.

Is Bad Breath a Disease?

Current scientific thinking is the oral malodor is normal. It is not disease. Mouth odor occurs sometime in nearly everyone; a study has shown that 9 out of 10 persons have what they, or someone else, considers to be bad breath. Bad breath itse has little, if any, correlation to systemic or oral disease. There is need to self-treat mouth odor wit medicated products.

Bad breath is common in the morning upon arising. During sleet the tongue, cheeks, and mouth are rest. Salivary secretion is minimand bacteria normally in the mourare active and forming volatile sulfocompounds which may cause mourage.

odor.

The lay public is convinced th "correcting" oral malodor is necess ry. Therefore, breath-freshening products constitute big business, review of how mouth odors can eliminated is in order.

There are four methods to effectively eliminate mouth odors. Priging can be accomplished by rinsi

the mouth with water (or a mouthwash), brushing the teeth (a more effective means), using dental floss, or eating high fiber food. Masking is the second method. As the name implies, this consists of replacing the natural odor of the mouth with a more pleasant one from a mouthwash or other means. Chemical neutralization of the volatile materials in the mouth is the third method.

Since the odor results from bacterial metabolic reactions, the fourth and most effective method for eliminating bad breath is via bacterial inhibition. Even so, the FDA advisory panel's report states that, to be truly effective, antimicrobial agents would need to be used daily every three to four hours. It does not consider this to be a "judicious" practice, and does not recommend unsupervised use of antimicrobial agents, especially when there are no symptoms and no disease.

Safe and Effective OTC Antimicrobials for Oral Health Care

After reviewing all of the available data, the panel could not find sufficient evidence to conclude that any antimicrobial should be given the 'safe and effective' classification. t found quite a few "needs more study" substances which are listed n Table 4. These agents can be subdivided into several categories: the quaternary ammonium compounds e.g., benzalkonium chloride), the olatile oils (e.g., eucalyptol), phenol lerivatives, oxidizing agents (e.g., lydrogen peroxide), and miscellaneous substances (e.g., alcohol, gentian iolet, povidone-iodine).

The quaternary ammonium comounds (QAC's) are undoubtedly afe, but evidence of effectiveness is acking. The proteins, neutralizing hemicals, organic materials and acterial by-products in the mouth verwhelm the antimicrobial action at QAC's exert when they interact with bacteria in a test tube.

The same holds true for the volale oil ingredients such as eucalypl, menthol, methyl salicylate and lymol.

Oxidizing agents include carbamle peroxide and its active principle, ydrogen peroxide. Hydrogen peroxle, when acted on by several en-

TABLE 4 Antimicrobials for Oral Health Care*

A. Proven Safe and Effective: None

B. Safe But Insufficient Evidence to Prove Effectiveness:

Benzalkonium Cl Iodine Benzethonium Cl Menthol Benzoic acid Methyl salicylate Carbamide peroxide Oxyquinoline SO₄ Cetalkonium Cl Phenol Cetylpyridinium Cl Phenolate sodium Chlorophyl Povidone-iodine Dequalinium Cl Secondary Domiphen Br amyltricresols Ethyl alcohol Sodium caprylate Eucalyptol Thymol Gentian violet Thymol iodide Hydrogen peroxide Tolu balsam

C. Unsafe and/or Ineffective:

Boric acid	Meralein sodium
Boroglycerin	Nitromersol
Camphor	Potassium
Cresol	chloride
Ferric chloride	Sodium
	dichromate
	Tincture of myrrh
****	TD 4 = /0.0

as published by FDA, 5/82

zymes (catalase most importantly), decomposes into oxygen which can kill microorganisms before it is transformed into elemental oxygen which then bubbles up. This debriding action helps clear debris out of ulcers and wounds. However, it has also been found that most bacteria are partially or completely resistant to the germicidal action of peroxides. Their effectiveness as antimicrobials is now being questioned.

Although **chlorophyll** is a popular ingredient in "breath mints," evidence that it is an effective antimicrobial does not exist. We do know that chlorophyll is safe and it is green.

Ethyl alcohol is known to kill microorganisms by denaturing and precipitating their proteins. However, the only studies conducted to date involve concentrations that are too irritating to oral ulcerations or inflamed mucous membranes for antiseptic use.

Gentian violet, long used as an antibacterial, anthelmintic and antifungal agent, has been replaced by newer, more effective, and nonstaining agents. It is still considered to be an effective agent for treating candidal infections (e.g., thrush) in

the mouth, but the diagnosis and treatment of thrush requires physician intervention.

Iodine is considered to be one of the most potent antimicrobials known. Povidone-iodine reportedly acts by slowly releasing iodine, thus reducing its toxicity potential. The problem with iodine itself is that it may actually injure tissue and delay wound healing. Phenol has similar actions.

The FDA panel feels that the above products, and the others listed in Table 4, have some, but inconclusive, evidence that they are effective. The panel has given manufacturers protocols to follow and time to prove the effectiveness of these ingredients. If manufacturers are not able to prove this, they will not be permitted to promote them for oral antisepsis.

Other agents such as boric acid, camphor and mercury-containing compounds have been ruled to be unsafe and ineffective for use as antimicrobial oral health care products (see Table 4).

Both the American Academy of Pediatrics and the FDA Advisory Panel on OTC Oral Health Care Drugs condemn the topical use of boric acid. In 1962, 172 cases of boric acid intoxication occurred resulting in 89 deaths. In 53 of these cases, the boric acid was applied topically for diaper rash and 23 infants died.

Astringents

Astringents precipitate proteins in living cells of mucous membranes, and form a protective film on the surface of the cells. This reduces the sensitivity of receptors to external stimulation. While the permeability of the cell membrane is decreased, the cell itself remains viable and there is no permanent injury to it.

In oral health care, astringents are used as "protective" coatings on irritated, inflamed, ulcerated, or abraded tissues. When effective, astringents will relieve pain and discomfort by this protective activity. They are not analgesics because astringents have no action on pain receptors.

Astringents found to be safe and effective by the OTC advisory panel are alum (ammonium, potassium, or sodium aluminum sulfate) and zinc chloride. Potassium aluminum sulfate is the most common of the three

alum forms used in medicine. In fact, its synonym is medicinal alum (also kalinite). Alum in a 0.2 to 0.5% solution provides a protein precipitating astringent activity with no corrosive effect on the mucous membranes. It is considered to be a safe and effective astringent that aids in the relief of sore mouth or sore throat. This action is symptomatic; alum does not have curative effects.

A 0.1 to 0.25% aqueous solution of zinc chloride is also a safe and effective astringent. Current theory is that the zinc ion provides the astringent action by precipitating proteins. It has the same indications as alum.

Debriding Agents

These are substances that soften, loosen, and remove exudates, mucus, and other secretions from the surface of lesions in the mouth and throat.

Two types have been proven to be safe and effective: the **peroxides** (hydrogen peroxide and carbamide peroxide), and **sodium bicarbonate**. The peroxides act as debriding agents by mechanically removing debris from tissue with which they come in contact.

Carbamide peroxide is comprised of urea and hydrogen peroxide in an anhydrous solution of glycerin. When it comes into contact with water, air or light, it slowly decomposes into its components. While it has a somewhat longer duration of action, both it and hydrogen peroxide exert the same actions.

When hydrogen peroxide comes in contact with tissues, it is converted into water and nascent oxygen which is claimed but not yet proven to be an antimicrobial. It is, however, an effective debriding agent. As elemental oxygen is formed, it bubbles up and loosens debris, mucus, pus and other materials present in wounds or ulcerations. It has very little action on intact skin or mucous membranes.

Sodium bicarbonate exerts its debriding action by mechanically washing substances off the surface of mucous membranes. It has a mucolytic action and disintegrates mucus by separating the protein in the mouth from polysaccharides which hold mucus together. Sodium bicarbonate also combines with tissue protein to form sodium albuminate

(soap) that softens and soothes epithelial tissue.

When used in the mouth or throat in a 5 to 10% solution, sodium bicarbonate loosens and softens mucus, thus facilitating expectoration. Its debriding action aids in the relief of pain and discomfort of sore mouth and throat.

Another peroxide product that has been used for years, but which this panel found to be unsafe and ineffective for OTC use as a debriding agent, is sodium perborate (Vincent's solution). The panel considered it to be unsafe because it is a boron derivative. When absorbed, it may be as toxic as boric acid. The panel concluded that it is ineffective because the quantity of oxygen released when sodium perborate is applied to tissue is insufficient to act mechanically as a debriding agent.

However, the status of sodium perborate is questionable at this time. In response to a similar finding by a panel that reviewed oral wound cleansers, FDA has countermanded the placing of sodium perborate in the "unsafe and ineffective" category.

On reviewing the comments and the additional data submitted after that panel's report, FDA concluded that sodium perborate was safe and effective for OTC use as an oral wound cleanser. The same potential exists for its use as a debriding agent.

Demulcents

Demulcents are substances that form viscous solutions in water and a cohesive protectant film on the surface of tissues to which they are applied. Pharmacologically they are inert and do not react with tissue. Nonetheless, they are considered to be drugs because they prevent access of irritating and sensitizing substances to inflamed or ulcerated tissue.

Many different substances exert demulcent activity including natural gums, mucilages, starches, polysaccharides, colloidal materials, and other high molecular weight polymers. Those stated to be safe and effective for OTC oral health care use are gelatin, glycerin, pectin, and elm bark.

Gelatin is a protein material obtained from collagen by-products of animal origin, or made synthetically.

Although it is digestible, it does provide a protective coating over irritated or ulcerated areas in the mouth and throat. It is most commonly used in lozenges for this purpose.

Glycerin mixed in 2 to 3 parts water is also an effective demulcent. It coats mucous membranes with a thin adherent film, thus providing a protective coating. Higher strengths should not be used because they car cause a burning sensation which is irritating but not dangerous.

Pectin is also a protectant. Wher mixed with water, it forms a suspen sion of highly hydrated particles which cling to and form a cohesive film on irritated, inflamed, or ulcerated mucous membranes.

"Slippery" elm bark was used fo medicinal purposes long before the FDA was established. It comes some what of a surprise that a group of scientists has been able to prove that a "old time" home remedy is indeed safe and effective drug.

The panel found enough data trule that 10 to 15% ground elm bark formulated with gums or agar as lowenges, yielded a mucilage whe placed in the mouth. This mucilage forms a protective barrier over irretated and inflamed mucous men branes.

Decongestants and expectoranter are two categories of agents that at claimed to be effective in oral healt care, but they have not yet been proten.

Both phenylephrine and pheny propanolamine are sympathomime ic decongestants. They have bees sold in this country in lozenge for for the relief of sore throat. Pheny propanolamine relieves nasal cogestion when taken orally and pheylephrine when applied topical But there is still no evidence the they produce any direct beneficity effect by topical application on so throats.

Certain expectorants, i.e., amm nium chloride, horehound, and to balsam, are also promoted for reliof sore throat. As a group, the expetorants have not (with the exception of guaifenesin in higher than precously recommended doses) be proven to be of any greater benefit: relieving cough than drinking lots fluids. The panel concluded that thuse of expectorants is based on traction, hearsay, and empirical impresions rather than scientific fact.

The above agents have not been shown to be effective in alleviating sore throat. Table 5 represents a summary of currently safe and effective oral health care products.

TABLE 5 Safe and Effective OTC Oral Health Care Products*

1) Anesthetics/ analgesics

Aspirin
Benzocaine
Benzyl alcohol
Dyclonine HCl
Hexylresorcinol
Menthol
Phenol

Phenolate sodium

Indication

For the temporary relief of occasional minor irritation, pain, sore mouth and sore throat

2) Astingents

Salicyl alcohol

Alum Zinc chloride

Indication

Aids in temporary relief of occasional minor irritation, pain, sore mouth and sore throat

3) Debriding Agents Indication

Carbamide peroxide Aids in removal of Hydrogen peroxide phlegm, mucus, or Sodium bicarbonate other secretions in

Aids in removal of phlegm, mucus, or other secretions in the temporary relief of discomfort due to occasional sore throat or sore mouth

1) Demulcents

Elm bark Gelatin Glycerin Pectin Indication

Aids in temporary relief of minor discomfort and protects irritated areas in sore throat and sore mouth

conclusions of an FDA advisory panel

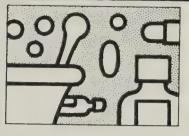


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Things You Should Know FOR YOUR GOOD HEALTH



Selecting the Right Pharmacist

Most people give little thought to their choice of a pharmacist. Too often a prescription is taken to be filled to the pharmacy closest to the doctor's office or to the patient's home. When a pharmacy is located in a specialty store, such as a grocery store which is frequented, that pharmacy may be preferred. Physical accessibility is certainly one of the things that should be considered in selecting a pharmacy, but there are others:

- Can the pharmacist be easily reached by phone?
- What happens if you have an emergency in the middle of the night, or on a weekend, or on a holiday when the store may be closed?
- . Do they deliver?
- Can you charge your prescriptions?
- Will they accept your prescription insurance plan? Medicaid?
- Is the pharmacist willing to answer questions and discuss your medications with you?
- Does the pharmacy keep patient profiles? A patient profile is a record of all prescriptions and, ideally, non-prescription medicines being taken by each patient so that sound advice can be given about the medication's uses and interactions. Filling all prescriptions at the same pharmacy assures the completeness of this important record.
- Does the pharmacy offer hypertension screening or blood pressure monitoring? Blood sugar testing for diabetes?
- Does the pharmacy carry medical equipment (crutches,

- wheel chairs, ostomy supplies, etc.).
- What other professional services does the pharmacy offer?
- Does the pharmacist discuss generic medications with you?

Drug interactions between prescription and non-prescription medications can often be avoided by consulting with your pharmacist. When choosing a non-prescription medication discuss with your pharmacist any ingredients to which you may be allergic or sensitive and which should therefore be avoided.

In selecting a pharmacist, you must decide what services are most important to you. Recognition must also be given to the pharmacist and his or her business which faces the same effects of inflation that you face. The increase in services, including personnel time to complete insurance forms, can add to your costs. Only you can say whether the services provided are worth the price to you. If your health insurance plan does not adequately cover the services you need, you can help your pharmacist continue to provide the service you want. Ask for recognition from your health insurance plan company of inequities in the benefits you and your pharmacist may experience under the program and request appropriate changes in those benefits.

Select your pharmacist as carefully as you choose your doctor and stay with the same pharmacy. In this way, your special needs can be monitored consistently by your professional pharmacist.

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Dean William J. Kinnard, Jr. served as Toastmaster for the 1985 Annual Convention Banquet.



William Skinner delivered the Simon Solomon continuing education program and discussed Pharmacy leases, Pharmacists as expert witnesses, and filing a personal will.



Al Cataldo, Director of Professional Affairs for the McNeil Co., presented a continuing education program on Pharmacists Against Drug Abuse as part of the regional Kappa Psi Convention in Baltimore April 13th.



Betty Alpern, President of the Ladies Auxiliary of the MPhA, introduced the other members of her Board at the annual Banquet.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

CALCIUM SUPPLEMENTATION:

Over 100 women in their early postmenopausal years were given various amounts of calcium supplements and bone mineral content was measured every three months for two years. Supplemental calcium amounts as high as 2000 mg daily did not protect against mineral loss. The reduction in mineral content of their bones was identical to that seen in women taking less than 550 mg of calcium per day. *Br Med J*, Vol. 289, #6452, p. 1103, 1984.

ZIMELIDINE:

Zimelidine is an antidepressant which has been found to inhibit the uptake of serotonin. Administration of the drug to humans and animals has been associated with increased abstinence from alcohol. Alcohol has been found to decrease the metabolism of zimelidine to norzimelidine, but the antidepressant mechanism of action with respect to reducing alcohol intake is yet unknown. Clin Pharmacol Ther, Vol. 36, #5, p. 654, 1984.

UNRECOGNIZED MYOCARDIAL INFARCTION:

A study involving over 5000 patients, of whom over 700 experienced a myocardial infarction, indicates that silent or atypical myocardial infarctions may be responsible for as much as 25% of the cases of attacks reported over a period of a year. These were found only upon biennial electrocardiographic examinations at times of routine check-ups. The silent infarcts are more common in women and older men but consequences are as serious as those which characteristically produce the classical symptoms of myocardial infarction. *N Engl J Med*, Vol. 311, #18, p. 1144, 1984.

ALCOHOLISM:

Over 250 men receiving liver biopsies were determined to be free of cirrhosis. Over a 13 year period of time, 38 of these men developed cirrhosis. Men with higher degrees of steatoses at the time of primary biopsy were more at risk of developing ethanol cirrhosis than others. It is suggested that identification of factors such as these which predispose a patient to cirrhosis may be useful in counseling patients to avoid the abusive use of ethanol, and may serve as an indication of the risk of alcoholic cirrhosis. *Lancet*, Vol. II, #8397, p. 241, 1984.

MORPHINE AND GLUCOSE LEVELS:

Low doses of opiates produce no alterations in blood sugar, but high concentrations can lead to hyperglycemia. The mechanism of opiate-induced hyperglycemia is apparently related to interaction with non-mu receptors in the CNS or the liver. *J Clin Invest*, Vol. 74, #4, p. 1473, 1984.

DES IN MALES:

Studies have linked the use of diethylstilbestrol (DES) to abnormalities found in cervical and vaginal tissue of offspring of mothers receiving the drug during pregnancy. Early studies suggested that effects in the male offspring were likely to be found and subsequent studies stated that such an association was indeed present. Current information obtained by examining a large group of men indicates that men who had been exposed to DES in utero have had no difference in the risk of genitourinary tract abnormalities, infertility or testicular cancer. Previous reports may have obtained inaccurate information because of selection biases and/or differences in diethylstilbestrol use. *JAMA*, Vol. 252, #21, p. 2984, 1984.

LIDOCAINE:

The duration of action of lidocaine is primarily dependent on hepatic action. Drugs which alter flow to the liver or reduce hepatic metabolic activity can cause lidocaine to accumulate. Nadolol (Corgard) and propranolol (Inderal) were administered to patients receiving the antiarrhythmic/anesthetic, and levels were increased. In both cases, it appears that the potentiation is due to a drug-induced reduction in hepatic blood flow rather than to an effect on the metabolic activities of the liver. Clin Pharmacol Ther, Vol. 36, #5, p. 584, 1984.

OREGON STATE PHARMACEUTICAL ASSOCIATION

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Position Available: Executive Director. The Oregon State Pharmaceutical Association is seeking qualified candidates for the position of Executive Director.

Candidates with a background in pharmacy are preferred but not required.

Administrative training and/or experience is required. Candidates should be able to demonstrate: executive leadership capabilities, management abilities, an understanding of legislative regulatory and political processes, and possess strong oral and written communication skills.

Preference will be given to candidates having formal training, post graduate instruction and experience in association management or administration.

Qualified candidates should submit resume, references and present compensation, no later than July 1, 1985. All information submitted will be treated in a confidential manner consistent with the requirements of the search process. Position available September 1, 1985.

Required information should be mailed to Mike Patrick, President, Oregon State Pharmaceutical Association, P.O. Box 517, Redmond, OR 97756.



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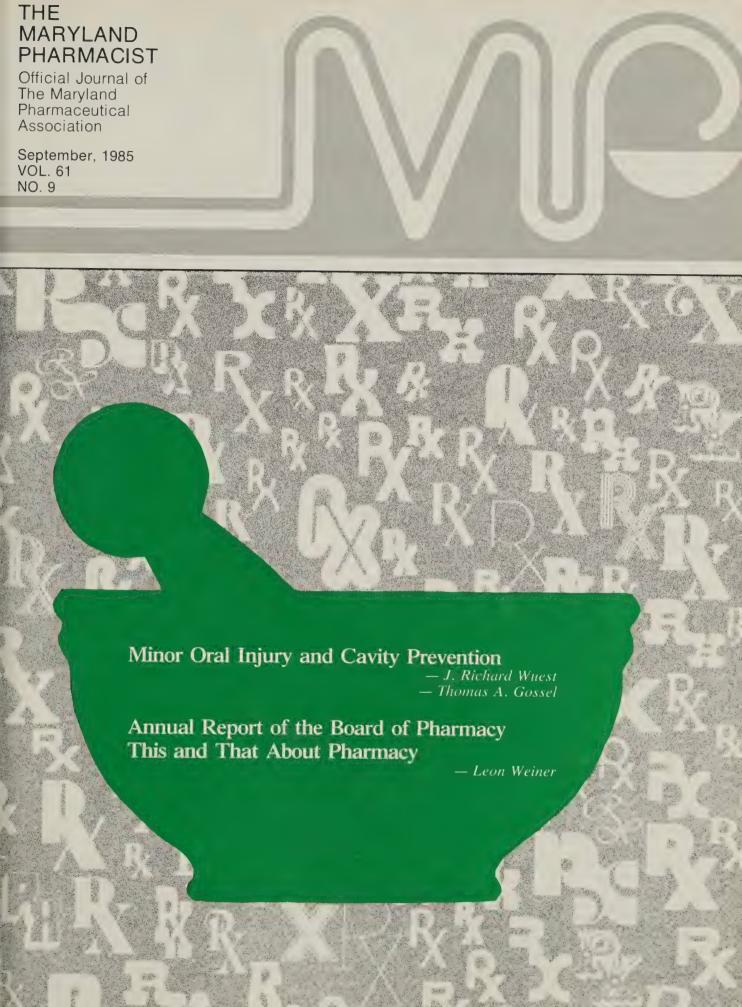
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JUMP ON IN!! JOIN!

I'll never forget the first time I met MPhA executive director, Dave Banta. It was during my last year of Pharmacy School when I had an opportunity to visit the Kelly Building to ask for some information. I expected to find some old sleek, "fat cat", cigar in hand, feet up on the desk. Instead, a young, dynamic gentleman, shirt sleeves rolled up, elbow deep in paper work, looked up, moved the papers aside, and said, "Hello, I'm Dave Banta! What can I do for you?"

And that, essentially, is what MPhA is all about . . . what the Association can do for you. We have a political function. We represent Maryland pharmacists in the state, local and federal legislative arena. We have a professional function. We provide a forum for practitioners to learn, to share ideas, to support each other and to grow. We have an economic function. We support adequate reimbursement for pharmaceutical services and coordinate efforts among practitioners to represent our professional services before the third party payors. We have a benefit function. We offer special programs for life and health insurance, liability and disability, as well as programs which provide educational and recreational benefits to our members. We have a social function. We hold meetings, sponsor group functions and provide the mechanism for pharmacists with similar interests to gather together.

In order to be responsive to our membership we need more than just dues. We need input and participation from our members to learn how we can continue to meet your needs and to grow with our members. For my project, as your president, I have proposed the establishment of a "Young Pharmacists' Caucus" specifically aimed at the younger pharmacists involved in ALL areas of pharmacy practice. We do not see many of the recent graduates at our meetings or involved in association committees. Therefore I am actively recruiting a "core" of younger pharmacists who, we anticipate, will become more vocal in Association work to guide leadership and to become leadership. This group will meet together early in the Fall, at a dinner meeting sponsored by the Association's Board of Trustees, to express their interest, ideas and concerns regarding directions of the Maryland Pharmaceutical Association.

I welcome and encourage your support of this effort, and would ask too, "What can I do for you?" I hope you will Jump On In and JOIN with me.

Madeline Feinberg, Pharmacist
1985-86 PRESIDENT

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II. NO. 7

Advising Consumers on OTC Products for Minor Oral Injury and **Cavity Prevention**

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and

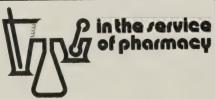
Thomas A. Gossel, R.Ph., Ph.D. Professor of Pharmacology and Toxicology **Ohio Northern University** Ada, OH

Goals

The goals of this lesson are to:

define terms relating to OTC anticavity products;

explain how to advise patients on self-medication of minor oral injury and cavity prevention.



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC. © Merrell Dow

Objectives

At the completion of this lesson, successful participants will be able to:

- recognize safe and effective OTC agents for treating minor oral injury and for cavity prevention;
- identify the pharmacologic action of these agents;
- explain the proper technique for applying these products.

Glossary of Anticavity Products

- Abrasive: a solid material with the function of cleansing or polishing. Abrasives are important inactive ingredients in anticaries dentifrice formulations and typically comprise up to 50 percent of the total formulation. Abrasives are added to dentifrices to facilitate mechanical removal of dental plaque, debris, and stain from tooth surfaces.
- Cementum: bone-like material covering the root of the tooth. Cementum contains about 45 to 50 percent organic and, the balance, inorganic matter. It contains a great number of fibers which attach the tooth to the
- Dental Calculus: mineralized 3. dental plaque that accumulates on the tooth surface principally at the gingival margin. One of the major fates of plaque is mineralization. Plaque serves as a matrix for calculus formation. The surface of calculus is usually covered with a nonmineralized layer of plaque.
- Dental Fluorosis: a mottling (discoloration) of tooth enamel resulting from imperfect mineralization associated with excessive ingestion of fluoride. Brown or black stains develop because the poorly calcified surface absorbs colored materials. The fre-

quency and extent of dental fluorosis is chiefly related to the fluoride content of drinking water.

Dental Plaque: a gel-like mat firmly attached to the surface of a tooth or restoration, but removable from exposed areas by thorough mechanical cleansing; the gel-like mat is made up of the following:

a. Microbial Masses. Microorganisms are the dominant components of mature plaque. The microbial composition of plaque is complex, but in general, an in itial predominance of gram positive organisms eventually shifts to gram-negative, along with a shift of aerobes to anaer obes.

b. Intermicrobial Matrix. Thi is a polysaccharide-proteir complex derived from the bacte ria, the saliva, and in areas adja cent to the gingival tissues, fron gingival fluid. Of the polysac charides, dextran and levan ar the most significant; both are ex tracellular polysaccharides pro duced by bacteria. Dextran is th more significant because of it greater quantity and relativ insolubility; levan is a muc smaller component of the matri and is used as a carbohydrate ni trient by plaque bacteria in th absence of exogenous sources.

c. Nonbacterial Cellular Incli sions. Both the epithelial cel derived from the tissue in th crevices between teeth and th leukocytes migrating across th area contribute to plaque form

tion and structure.

Enamel: the compact and has substance that covers the crow of the tooth and provides prote tion for the dentin. The inorga ic content of mature enamel 96-97 percent, the remaind consisting of organic matter ar water.

7. Pellicle: a product of saliva which is bacteria-free and contains glycoproteins, derivatives of glycoproteins, polypeptides, and lipids. A cleaned tooth surface will form a pellicle within minutes. The formation of this structure is believed to be the first step in plaque formation, although not always a necessary prerequisite.

This lesson continues and concludes the review of OTC oral health care drugs by presenting information on oral wound cleansers, oral wound healing agents, and anticaries (anticavity) products. The Glossary of Oral Health Care Terms appears with a previous lesson, Advising Consumers on OTC Products For Relief of Oral Discomfort. Terms specific for this lesson are repeated above.

Oral Mucosal Injury OTC Drug Products

The Food and Drug Administration (FDA) reviewed two groups of therapeutic agents used for oral nealth care separately from the others previously mentioned in SCOPE articles. They are the agents for oral nucosal injury, i.e., the oral wound cleansers and the oral wound healng agents.

TABLE 1 Safe and Effective Oral Wound Cleansing Drug Products*

Carbamide peroxide 10%
— in anhydrous glycerin

- in annyurous grycer

Iydrogen peroxide 3%— in aqueous solution

odium perborate monohydrate
— 1.2 gram dry powder to be
dissolved in 30 ml of water

adications:

For temporary use in cleansing minor oral wounds or gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury or other irritations of the mouth or gums.

For temporary use to cleanse canker sores.

Assists in the removal of foreign material from minor oral wounds.

Physically removes debris from minor oral wounds.

s published by FDA, July 1983

Minor gum disorders caused by mild trauma or irritation have long been considered self-treatable. OTC products effective for this use should either cleanse or promote healing, and aid in the formation of new, healthy tissue.

Officially, oral wound cleansers are defined as "nonirritating preparations which assist (physically or chemically) in the removal of foreign material from minor oral wounds and do not delay wound healing." Most of the agents contain oxygen releasing compounds which react with tissue or salivary enzymes and produce a "foaming" action. This action physically removes debris from the wound to which it is applied. Table 1 lists the agents ruled to be safe and effective, and their indications.

Oral wound healing agents are "nonirritating agents which aid in the healing of minor oral wounds by means other than cleansing and irrigating, or by serving as protectants." Several factors involved in wound healing have been identified (see Table 2), but three stages are basically involved: inflammation, proliferation, and reorganization of tissue.

TABLE 2 Factors Involved in Wound Healing

A) Systemic

- physiological condition
- nutritional state
- hormone levels and production

B) Local

- blood and oxygen supply
- presence of infection
- presence of foreign material
- mobility of tissue
- extent of wound
- type of tissue injured

Over the years, considerable research has been undertaken to develop substances that will accelerate wound healing. But, none has yet met the test of conclusive proof of effectiveness. For the present, it is best to prevent complications and retardation of wound healing so the body's own mechanisms can regenerate and heal itself.

There is no evidence that reducing inflammation, e.g., applying cold to traumatic injuries and burns, is beneficial in treating oral wounds. Likewise, there is no proof that modifying cell proliferation is helpful in these injuries.

Since collagen is the basis of scar tissue, any agent that increases the rate of normal collagen synthesis could be beneficial in producing a more rapid rate of wound healing. Several substances (e.g., allantoin, chlorophyll) have been promoted as topical healing agents, but none has yet been proven effective. Controversy rages in both the scientific and lay press as to whether vitamins (especially vitamin C) and modified proteins are effective in reducing wound healing time. The quest for an effective oral wound healing agent continues.

Oral Wound Cleansers

Both carbamide peroxide 10% in anhydrous glycerin, and hydrogen peroxide 3% have been shown to be safe and effective for this use. When carbamide peroxide is exposed to air. light or water, it decomposes into its components: 70% urea and 30% hydrogen peroxide. It is formulated in anhydrous glycerin. Urea is a normal body constituent which does not exert action in the mouth. Hydrogen peroxide, whether it results from the carbamide peroxide or is directly applied as a 3% solution, reacts with enzymes (catalase and peroxidase) from saliva to form water and oxygen. The free oxygen causes the bubbling, foaming activity.

The advisory panel placed **sodium perborate** in the "banned from future sale" category. The panel felt that the risks of toxicity (a source of its active ingredient, hydrogen peroxide) as compared to the benefits (hydrogen peroxide is available in other forms) did not justify its continued OTC availability. The panel's concern about toxicity was due to the boron content of sodium perborate and the known toxicity of boric acid.

However, the FDA reviewed all comments sent to the agency following publication of its advisory panel's report (1979), as well as data not available to the panel. In 1983, FDA reversed the decision and concluded that sodium perborate was safe and effective for OTC use as an oral wound cleanser. FDA felt that the toxicity of boric acid could not be assumed for sodium perborate. The National Clearing House for Poison

Control Centers reported only 26 accidental ingestions of sodium perborate over a nine-year period. These ingestions were fewer than those encountered with boric acid. None of the individuals involved required hospitalization. There were no fatalities, and only two complained of symptoms.

Therefore, because of its history of safe marketing and the fact that it decomposes in water into hydrogen peroxide in concentrations similar to half-strength hydrogen peroxide (which is an effective wound cleanser), FDA placed it in the same category as hydrogen peroxide and car-

bamide peroxide.

The label indication for canker sores created another controversy between FDA and the panel that reviewed it. The panel concluded that the term canker sore is vague to most consumers, that canker sores cannot be self-diagnosed, and that they are not amenable to self-treatment. FDA reversed this conclusion by stating, "while the cause of canker sores may not be definable by the consumer, topically applied oral wound cleansers could provide a useful function by removing debris that might be lodged in ulcerated tissue of a canker sore." Therefore, FDA added this indication to the proposed product labeling of these agents.

Oral Wound Healing Agents

Four substances were studied for this indication: allantoin, carbamide peroxide, chlorophyll, and hydrogen peroxide. None could be proven effective in promoting healing.

Carbamide peroxide and hydrogen peroxide, as stated earlier, are effective wound cleansers, and, therefore, will indirectly aid healing. There is no evidence that they directly enhance collagen formation. It is theorized that these agents may exert this action by supplying oxygen to the tissue, increasing its consumption, and accelerating connective tissue and collagen synthesis. However, these actions have not been proven. Thus, the FDA placed these two agents in the "needs more study" category.

Allantoin has been used for over 70 years as a "growth stimulant" for abscesses, burns, ulcers and wounds, psoriasis and numerous

other skin conditions. There is no doubt it is safe. However, no one has undertaken the double blind, crossover studies to prove efficacy required since enactment of the 1962 Amendment to the Pure Food and Drug Act. Statements of effectiveness based on testimonials and empirical impressions are not valid. Therefore, allantoin is in the "needs more study" category.

Chlorophyll shares the same status. Chlorophyllins are the water soluble components of chlorophyll. There is a variety of reports in the literature stating that chlorophyllins induced healing in wounds and ulcerations that did not respond to other treatments. As with allantoin, these reports are anecdotal and not clinically proven. Until they are, none of the above agents will receive the FDA "seal of approval."

Consumer Advice

There are two "acceptable" methods of properly applying carbamide peroxide (e.g., Gly-Oxide^R). The first is by direct application (several drops) onto the affected area of the mouth. The medication should remain a couple minutes before it is expectorated. For use as an oral rinse, the second method, 10 to 20 drops should be placed on the tongue and mixed with the saliva in the mouth. After swishing around the mouth and the affected area for at least one minute, the person should then spit out the rinse.

Hydrogen peroxide should be used in a similar manner. When directly applied, several drops of full strength (3%) solution should be placed on the affected area. For oral rinsing, the 3% solution should be diluted in half with warm water.

For sodium perborate, the manufacturer usually suggests mixing one-capful (which is equivalent to 1.2 g) with one-ounce of warm water. This resulting solution should be rinsed around the mouth for at least one minute. Special care should be taken not to swallow the sodium perborate solution.

With any of the above agents, the recommended frequency of use is four times per day.

If the condition does not improve within seven days, the individual should contact a doctor or dentist. A

serious disease, such as peridontal disease or cancer, may be present.

Anticavity Drug Products

Undoubtedly the most significant outcome of the FDA review of OTC dental products to date is the switch of fluoride rinses and gels from prescription only to OTC status. The advisory panel that reviewed anticaries (anticavity) drug products recommended that these products be made available for self-medication provided they do not contain more than 120 mg fluoride, and that they be marketed in child-resistant containers.

While the FDA has not yet officially ruled on this, many manufacturers have already made the switch for their products. FDA must determine whether the fluoride rinses and gelebenefit persons who also use fluoride dentifrices, those who live in areas of the country where adequate levels of fluoride are already in their water supply, or those who are receiving fluoride treatments fron their dentists.

Dental caries is a term more commonly referred to as cavities. We will use the two terms interchangeably in this lesson. It is reportedly one of the most common diseases in humans especially in this country where we eat so many refined and sugar containing foods. However, the exact cause of dental cavities has not yet been determined. Officially, it is a "disease of the calcified tissues of the teeth characterized by deminer alization of the inorganic portion and destruction of their matrix."

Plaque is the major contributor factor, since it concentrates acide forming bacteria at specific sites of teeth. This begins the demineralization of tooth structure and initiate the first step in cavity formation. These bacteria utilize sugars to produce acids. The implication is the higher the intake of sucrose, the greater the incidence of dental cases. Sucrose content is high chewing gum, candies, "sugared vitamin" cereals, and so drinks.

Cavities occur when the teeth a susceptible to demineralizatio acid-producing bacteria colonize the teeth, and these bacteria a "fed." The first and second facto can be controlled, but the third I

quires personal motivation to limit carbohydrate intake. Study after study has reported a lower occurrence of cavity formation when sugar intake is restricted. Nonetheless, the American public doesn't heed this advice.

Fluoride exerts a protective action against cavity formation. It is incorporated into developing teeth especially in the enamel surface as an insoluble substance called fluorapatite. After teeth have formed and erupted through the gums, saliva helps protect teeth against cavity formation by providing mineral ions that can be incorporated on the enamel surface.

Calcium and phosphate, normally present in saliva, serve this function. But, when fluoride is also present, he remineralization (antidemineralzation) process is enhanced. This is ntensified by applying fluoride diectly to the teeth, and rinsing fluorde salt over and around the teeth so hat it can be incorporated into plaque. Fluoride can be provided by naturally high levels in drinking water, addition to the water supply it the processing facility, vitamin preparations (to remain prescriptiononly since oral ingestion is different rom rinsing with an agent that is not wallowed), topical treatment by a lentist, fluoride-containing dentirices, and fluoride containing gels nd rinses. Since everyone does not lave access to the first four means of upply, the panel concluded that fluride gels and rinses should be made vailable without a prescription to oin the dentifrices which have alvavs been OTC.

Studies have shown that daily inses with sodium fluoride solution re the most effective means of preenting dental cavities.

The second factor in controlng dental cavities is removing/ thibiting the acid-producing bactea in the mouth, especially in laque build-up. This can be satisictorily done with adequate brushig, and the use of abrasiveontaining dentifrices.

The commonly used abrasives are lumina, dicalcium phosphate. halk, insoluble metaphosphate MP), calcium pyrophosphate and lica-containing substances. By menanically removing dental plaque nd debris from tooth surfaces, they

cleanse them of bacterial growth and retard tooth decay. This can be further enhanced by the addition of fluoride to the abrasive dentifrices.

Are Fluoride Rinses and Gels

Fluoride can be extremely toxic; it may be lethal to a 70 kg man in doses approaching 5 grams. The likelihood of toxicity, however, is remote unless the individual willfully swallows the substance.

Studies have shown that inadvertent ingestion is rare in children who have developed control of their swallowing reflex and are instructed to use the rinse properly. The majority of children aged three to six swallowed less than 0.5 g in toothpaste, and none studied swallowed more than one gram. Toothpaste contains less than 1% sodium fluoride.

While it is conceivable that continually swallowing these products and drinking fluorinated water could provide acute fluorine intoxication, this has not happened in over 20 years of experience. The only reported severe adverse effect to fluoride products, or fluorinated water, is permanent mottling of the teeth due to imperfect mineralization of enamel. This occurs, however, when high levels of fluoride (greater than 20 ppm water) are ingested while teeth are being formed (under the age of

As an edge against potential toxicity, the advisory panel has recommended that dental gel and rinse packaging contain no more than 120 mg of fluoride, and that dentifrices be limited to 260 mg per package.

Are Fluoride Containing **Products Effective?**

Several dozen large-scale clinical trials have been performed using these agents. Documented results prove that the products are indeed effective. One particular study has reported a 20-50% inhibition of dental cavities by these agents.

Sodium fluoride, stannous fluoride, and phosphate fluoride complexes have been accepted as safe and effective for OTC anticavity use (see Table 3).

TABLE 3 Safe and Effective OTC Anticaries (Anticavity) Products*

As a Dentifrice

Sodium fluoride (0.22%) Sodium monofluorophosphate (0.76%)Stannous fluoride (0.4%)

Stannous fluoride (0.4%)

As a Rinse

Acidulated phosphate fluoride (0.02%)Sodium fluoride (0.05%) Stannous fluoride (0.1%)

*as determined by FDA or its Advisory Panel on OTC Anticaries Agents

A special note should be made about stannous fluoride products. They are effective, but their aqueous solutions are unstable. A white precipitate is formed within a few minutes after preparation. The dentifrices have been stabilized, and the gel forms contain anhydrous glycerin as the vehicle to avert the problem. The rinses, however, must be prepared immediately before use to assure stability and effectiveness.

Another difference between stannous fluoride products and the other anticavity agents is that stannous fluoride will stain the teeth in some. but not all, individuals. This is due to a chemical reaction between the tin in stannous fluoride and plaque and debris on the teeth. It can be minimized by adequately brushing the teeth after applying the product. Since the stain does not occur on the teeth themselves, it is not harmful or permanent. The stain can be removed by a dentist, but affected individuals may want to use another anticavity agent.

Consumer Advice

Regardless of the dosage form, consumers should be advised to assure that children do not swallow the fluoride-containing products. There is little likelihood that these products will cause toxicity in adults. But, children under six should be supervised because developing teeth can be permanently discolored if excessive fluoride is swallowed.

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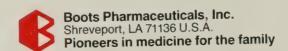
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brush before a thorough brushing. This should be done at least once a day unless the dentist advises more often.

The consumer should use approximately 10 milliliters of a dental rinse freshly prepared if it is stannous fluoride), swish it around in the mouth or at least one minute, and expecto-

rate it. They should not eat or drink for one-half hour afterwards to give the product adequate contact time with the teeth.

The consumer should first brush the teeth thoroughly and rinse the mouth before using a **dental gel**. The gel is then applied to the teeth, according to the manufacturer's directions, and spread with a toothbrush. It should remain on the teeth for at least one minute before expectorating. Again, the individual should not eat or drink for thirty minutes after this process.

This concludes the review of OTC oral health care drug products.

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—\$.02 per coupon; 500 to 1000 coupons—\$.02.5 per coupon; and batches of 1000 coupons and over—\$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.

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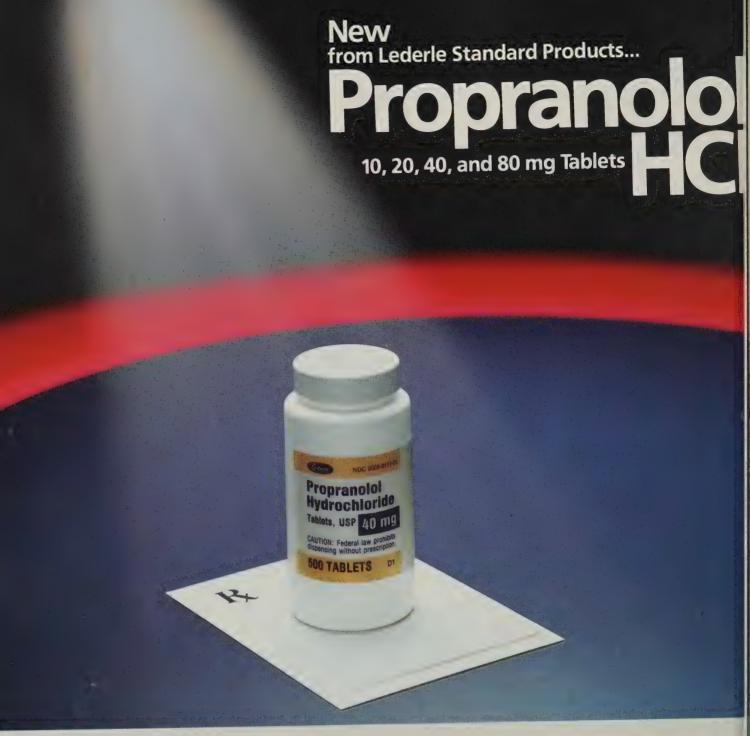
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periodicals to your customers, you should be. Just ask us how profitable it can be. And if you do have a magazine department, chances are your operation has outgrown it and it should be expanded. Call Jim Trosch or Pete Van Poppel today at (301) 233-4545.





PROPRANOLOL HCI CONTRAINDICATIONS

Propranolol HCL is contraindicated in 1) cardiogenic shock 2) sinus bradycardia and greater than first degree block 3) bronchial asthma, 4) congestive heart failure (see WARN-INGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol HCl

WARNINGS:

CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congeshive heart failure, if necessary they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE continued use of beta blockers can in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely or propranolol HCI should be discontinued (gradually, if possible)

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of propranolol HCI therapy. Therefore, when discontinuance of propranolol HCI is planned, the dosage sho rid be gradually reduced over at least a few weeks and the patient should be cautioned against interruption or cessation of therapy without the physician should be cautioned against interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol HCI therapy and take other measures appropriate for management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at tisk of having occult atherosclerotic heart disease who are given propranolol for other molicultions.

NONALLERGIC BRONCHOSPASM (e.g., chronic bronchitis emphysema) --PATIENTS BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKER!

Propranolol HCI should be administered with caution since it may block bronchodilatio duced by endogenous and exogenous catecholamine stimulation of beta receptors

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therap to major surgery is confroversial. It should be noted, however, that the impaired ability cheart to respond to reflex adrenergic stimuli may augment the risks of general anesthes. surgical procedures.

Propranolol HCI, like other beta blockers, is a competitive inhibitor of beta-receptor ag and its effects can be reversed by administration of such agents e.g., dobutamine of proterenol However, such patients may be subject to protracted severe hypotension Eculty in starting and maintaining the heartbeat has also been reported with beta block.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appear of certain premonitory signs and symptoms (pulse rate and pressure changes) of acut hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of syntoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid.

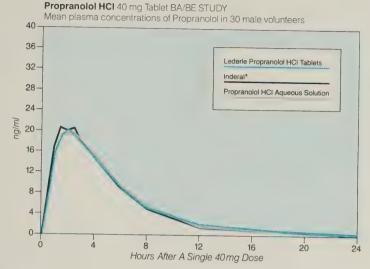
reported in which latter propranoiol, the tachycardia was replaced by a severe bradyc requiring a demand pacemaker. In one case, this resulted after attinitial close of 5 mg propranoiol IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME several cases have been

PRECAUTIONS

General Propranolol should be used with caution in patients with imparted neual-confunction. Propranolol HCris not indicated for the treatment of hypertensive emerger cit

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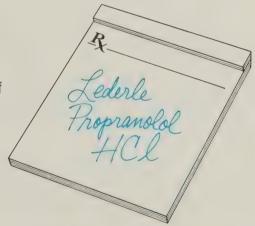
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adrenoreceptor blockade can cause reduction of intraocular pressure Patients should that propranolol HCI may interfere with the glaucoma screening test. Withdrawal may be a return of increased intraocular pressure

al Laboratory Tests. Elevated blood urea levels in patients with severe heart disease, ed serum transaminase, alkaline phosphatase, lactate dehydrogenase

in INTERACTIONS: Patients receiving catecholamine-depleting drugs, such as reser-should be closely observed if propranolol HCI is administered. The added catechol--blocking action may produce an excessive reduction of resting sympathetic nervous y which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or fatic hypotension

nogenesis. Mutagenesis, Impairment of Fertility: Long-term studies in animals have conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in ats and mice, employing doses up to 150 mg/kg/day, there was no evidence of signifing-induced toxicity. There were no drug-related tumorigenic effects at any of the dosvels. Reproductive studies in animals did not show any impairment of fertility that was table to the drug. table to the drug.

lancy, Pregnancy Category C. Propranolol HCl has been shown to be embryotoxic in I studies at doses about 10 times greater than the maximum recommended human

are no adequate and well-controlled studies in pregnant women. Propranolol HCl be used during pregnancy and well-controlled studies in pregnant women. Propran Is should be used during pregnancy only if the potential benefit justifies the potential

g Mothers Propranolol HCI is excreted in human milk Caution should be exercised vopranolol HCI is administered to a nursing woman

Fric Use Safety and effectiveness in children have not been established

ADVERSE REACTIONS

Most adverse effects have been mild and transient and have rarely required the withdrawal

Cardiovascular. Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type

Central Nervous System: Lightheadedness: mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia, visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics

Gastrointestinal: Nausea, vomitting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress

Respiratory: Bronchospasm

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura Auto-Immune. In extremely rare instances, systemic lupus erythematosus has been

Miscellaneous. Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practoloi) have not been associated with propranoiol

Annual Report of the Maryland Board of Pharmacy 1984–1985

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable Harry Hughes, Governor of Maryland and to the Maryland Pharmaceutical Association. This is the eighty-second report to the Governor and the seventy-second report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the fiscal year ending June 30, 1985. This report is also being submitted to the Secretary of Health and Mental Hygiene, the Mc-Keldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

MEETINGS

During the year the Board held twenty meetings, seven of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for registration of pharmacists.

OFFICERS

Bernard Lachman was elected President and Paul Freiman was elected Secretary-Treasurer of the Board.

PERSONNEL

The staff consists of Roslyn Scheer, Executive Director; Margaret Lloyd, Office-Clerk II, Dee Moore, Office Secretary and Patricia Cockrell, Steno-Clerk.

EXAMINATION

The Board conducted examinations for registration of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 26, 27, 28, 29, 1984 and September 24, 25, and 26, 1984.

The applicants who were examined in June of 1984 were licensed in July, 1984 which is in F.Y. 1985. There were eighty-six applicants for the Board in June 1984. Seventy-three passed both the theoretical and practical portions of the examination and were registered. Thirteen failed the examination.

Having previously passed the theoretical portion of the examination, four candidates took the practical examination in June. The candidates passed and were subsequently registered.

There were twenty-four applicants for the Board in September 1984 (F.Y. 1985). Nineteen passed both the theoretical and practical portions of the examination and were registered. Five failed the examination.

Data relative to the June 1985 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts. Part I is the NAPBLEX from the National Association of Boards of Pharmacy which consisted of the following subjects:

Chemistry
Pharmacy
Mathematics
Pharmacology
Practice of Pharmacy

Part II consists of: Laboratory Maryland Law Federal Law

The Federal Law Exam is obtained from NABP. The Maryland Law Exam was compiled by members of the Board. The laboratory examination, requires the compounding of four prescriptions per applicant. The following table shows the number of pharmacists who were registered by examination during the past ten years.

Stered by Charimation delives		
Year	Number of Pharmacists	
1975-1976	109	
1976-1977	166	
1977-1978	150	
1978-1979	137	
1979-1980	180	
1980-1981	183	
1981-1982	100	
1982-1983	116	
1983-1984	92	
1984-1985	92	
	the state of the s	

As in the past, many pharmacists applied for reciprocal registration in Maryland in order to accept positions with their employers who are opening stores in Maryland. Those applicants who did not meet our requirements concerning practical experience prior to or after registration in another state were advised that they must take our practical examination in order to verify their qualifications.

In all cases, an applicant for reciprocal registration must appear for a personal interview. The entire Board must act on whether or not to grant registration to such applicants, who must sign an agreement to comply with Maryland's law pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted registration by reciprocity and the number who were certified to register by reciprocity in other states during the past ten years.

•			
	Fiscal Year	Reciprocity	Certification
	1975-1976	89	44
	1976-1977	78	68
	1977-1978	91	77
	1978-1979	113	42
	1979-1980	73	69
	1980-1981	88	72
	1981-1982	85	51
	1982-1983	103	60
	1983-1984	119	58
	1984-1985	148	54
	TOTAL	987	595

The table shows Maryland gained 392 pharmacists by reciprocity during the past ten years.

New permits to operate a pharmacy were issued to ninety-six firms for the 1985 Fiscal Year.

PHARMACY PERMITS

Countie

Location	1984-1985
es:	
Allegany	2
Anne Arundel	2 3
Baltimore	20
Carroll	3
Charles	1 5
Dorchester	5
Frederick	3
Harford	3 5
Howard	
Kent	3
Montgomery	9
Prince Georges	5
Queen Ann's	2
St. Mary's	6
Talbot	2
County Totals	72
Baltimore City	24
State-Wide Totals	96

MANUFACTURERS PERMITS

State-Wide Totals

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics during 1984 were issued to three firms.

DANGEROUS DRUG DISTRIBUTORS PERMITS

The Board issued ten new permits to sell, distribute, give or in any way dispose of dangerous drugs during 1984.

OTHER PERMITS

The total number of pharmacies in the State of Maryland for 1985 fiscal year is 1,228 and the total number of pharmacists is 5.759.

LEGISLATION

The following legislation which effects the profession of pharmacy either directly or indirectly was enacted by the 1985 Maryland General Assembly. This list of Bills includes the purpose as it pertains to pharmacy.

HB 96—Extends under certain conditions the jurisdiction of certain boards to licensees who have surrendered or failed to renew their license.

HB 410—The power of the Secretary of the Department of Health and Mental Hygiene does not include the power to disapprove or modify any decision or determination of the Board under authority specifically delegated by law to the Board.

SB 710/HB 1572—Authorizes the Board to waive certain requirements for pharmacies engaged in pharmaceutical specialties.

SB 633/HB 1567—Allows the Board to maintain a record of the pharmacist's place of business or home

SB 754—Requires pharmacists to meet continuing education requirements prior to renewal of a license.

COOPERATIVE ACTIVITIES

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the University of Maryland-School of Pharmacy, the Maryland Pharmaceutical Association, the Federal Drug Administration, the Food and Drug Administration, City, County and State Police and all Boards and Pharmacy Schools throughout the country.

DISCIPLINARY ACTIVITIES

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints are received from the Division of Drug Control, Medical Assistance Compliance Administration, and the State of Maryland Courts. The wide range of complaints vary in severity. Listed below are statistics concerning the types of complaints received for the period April 1983 to April 1984.

miscellaneous*	57
mislabeled prescriptions	15
communication	5
incorrect drug dispensed	31
expiration date	1
generic substitution	7
refilling prescription without prescription	4
infrequently prescribed drug-hard to find	0
wrong dosage dispensed	4
Medicaid fraud	2
shortages of controlled drugs	5
concentrated form drugs	2
TOTAL CONSUMER COMPLAINTS	133

^{*} Complaints are on pricing, cleanliness, professionalism and store hours.

Fourteen pharmacists were charged with violation of the pharmacy laws. One formal disciplinary hearing was held; all other cases were resolved by Consent Agreements. Two pharmacists' licenses were revoked. Two pharmacists' licenses were suspended, immediately stayed and the individuals placed on probation under certain conditions. Three pharmacists' licenses were revoked, immediately stayed and the individuals were placed on probation under certain conditions. Four pharmacist's licenses were summarily suspended, and one pharmacy permit was summarily suspended. One pharmacist resigned his license with the posture of revocation. One pharmacist voluntarily decided to refrain from practicing pharmacy. Three licenses which had been suspended in a prior year were reinstated.

FINANCES

All funds of the Board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

FINANCIAL STATEMENT

The Board of Pharmacy had revenues of \$210,813 in 1983 and \$164,474 in 1984. The Board of Pharmacy had expenditures of \$95,865 in 1983 and \$120,632 in 1984. The Board's budget is \$128,712 for 1985 and \$137,065 for 1986.

OTHER ACTIVITIES

In addition to the President, Bernard Lachman and Secretary-Treasurer, Paul Freiman, the Board consists of the following commissioners: Ralph Small, Robert Snyder, Leonard DeMino, Anthony Padussis, Estelle Cohen, and

William E. Adams. All the Commissioners are registered pharmacists in the State of Maryland with the exception of Ms. Cohen and Mr. Adams who are consumer (public) members of the Board.

The Board promulgated or amended the following reg-

ulations:

- 1. Pharmacy Equipment;
- 2. Civil Penalties;
- 3. Closing of Pharmacy;
- 4. Experience Required for Licensure by Reciprocity.

At this time the Board is in the process of proposing for promulgation or amendment regulations concerning:

- 1. Parenteral/Sterile Enteral Compunding
- 2. Institutional Pharmacies

In 1985, the Board continued its excellent relationship with the Department of Health and Mental Hygiene. The cooperation and courtesy extended to the Board of Pharmacy by all members of the Department is appreciated by all the Board members.

Again the Board must commend our Executive Director, Roslyn Scheer, for her continued excellent management of the Board's business. Through her efforts the Board continues to operate smoothly and efficiently. In addition, the Secretary-Treasurer must commend all of our excellent secretaries Margaret Lloyd, Dee Moore and Pat Cockrell for their excellent work and cooperation.

All of the Commissioners actively participated by serving on various committees appointed by the President, attending numerous meetings through the State, and being available for consultations and special meetings when necessary.

During this year, the Board has increased its activities into the distribution of prescription medications in areas other than pharmacies. In cooperation with the Maryland Commission on Correctional Standards, regulations were promulgated which control the distribution of medication in all correctional institutions in Maryland.

This increased activity is a result of the Board members visiting various institutions throughout the State and reviewing their methods of dispensing and administering medication. As a result of these efforts, we believe that in the future recipients of prescription medication, wherever it is received in Maryland, will be assured of the same high standards and protection that exist in the licensed pharmacies in our State.

The Board of Pharmacy is working with the Committee for Impaired Pharmacists of the Maryland Pharmaceutical Association. The Committee is a viable support system of peers and acknowledged specialists working on the premise that chemical dependency is an illness of complex behavioral and physiological origins.

This year marks the end of the term for one member of our Board. Robert Snyder served ten years on the Board during which time he witnessed and participated in the growth of the Board of Pharmacy to its present status and served as its Secretary for a period of time. The Board of Pharmacy will sorely miss Dr. Snyder and wishes him well in his future endeavors.

Respectfully submitted,
Paul Freiman
Secretary-Treasurer

TO: All pharmacists

FROM: Gary M. Oderda, Pharm.D., M.P.H.

Director, Maryland Poison Center

DATE: June 24, 1985

RE: Maryland Poison Center Position Statement

on Ipecac Syrup

Because of recent negative publicity concerning abuse of ipecac syrup in patients with eating disorders, Dr. Gary M. Oderda, director of the Maryland Poison Center at the University of Maryland School of Pharmacy, has issued this statement of the Maryland Poison Center's position regarding ipecac syrup:

"Ipecac syrup is a safe and effective nonprescription drug used frequently in the treatment of poisonings and known to prevent serious injury and death. Since the use of ipecac syrup in the home setting prevents toxicity, avoids unnecessary delay in treatment and reduces health care expenses, the Maryland Poison Center urges people, especially parents, to obtain and keep a one-ounce bottle in their homes in case of a poisoning. Ipecac syrup should be used only on the recommendation of the proper instructions for its use. Ipecac syrup is not intended for repeated use and is contraindicated in certain poisoning situations."

We hope this statement will help reassure you and your clients about the safety of syrup of ipecac and the need to keep it readily available as a nonprescription drug. The Maryland Poison Center has poison information cards on syrup of ipecac available upon request at 25 copies free and \$1.00 for each additional 25 copies.

Kinnard Named Vice-Chancellor

Dr. William J. Kinnard, Jr., dean of the School of Pharmacy at the University of Maryland at Baltimore, has been named acting vice-chancellor for graduate studies and research effective July 1. In a letter to Dr. Kinnard, Dr. Edward N. Brandt, Jr., UMAB chancellor, noted that the appointment extends till January, 1986, when it is anticipated that a permanent vice-chancellor for both the UMAB and UMBC campuses will be announced.

Appointed dean of the School of Pharmacy in 1968, Dr. Kinnard also served as dean of the Graduate School from 1974–79, and presently serves as civilian consultant on pharmacy to the surgeon general of the United States Air Force. Earlier this year, Dr. Kinnard was given the Distinguished Pharmacy Alumnus Award by Purdue University, where he received his Ph.D. degree in 1957.

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Harrison, Pharm. D. Norwalk. California



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The Roche Community Pharmacy Advisory Board, representing independent pharmacies nationwide, is made up of community pharmacists—just like you. The members are selected for their leadership and outstanding commitment to their profession.

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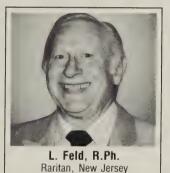
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THIS AND THAT ABOUT PHARMACY

by Leon Weiner, P.D.

Spotlight on HARRY FINKE, JR.

Harry Finke, Jr., UofMD 1977, is not the run of the mill pharmacist. As a matter of fact, he is the pharmacist on the run. He has run the Maryland Marathon four times in 1978, 1979, 1980 and 1981, with his best finish of 32nd out of 575 at three hours, 6 minutes. In addition, Dr. Finke has run in the 1982 Marine Corps Marathon, the 1983 Atlanta, GA Marathon and the 1984 Pensacola, FL Marathon. When asked why he runs so much, he answers "To keep my sanity and to eat anything I want to without worry." He has been jogging since 1969 and started serious running in 1975. At the present time, he runs about 50 miles a week, mostly in the morning before going to work.

Harry, age 36, is 5' 9" and weighs about 163 lbs. He graduated from Mount Saint Joseph High School in 1966, where he played varsity football and participated in varsity wrestling. Between 1968 and 1971, Harry served his military obligations with the Navy and spent sometime at Kamiseya, Japan. He then went to the University of Maryland School of Pharmacy graduating in 1977. After graduation, he went to work for the Maryland Poison Information Center. In August 1978, Harry opened up his Medicine Shoppe at 7116 Darlington Drive which he is currently operating. His wife Patricia, who is the store bookkeeper, is the mother of his two children, Jeff, 15 years, and Eric, 7 years.

Dr. Finke has two goals: 1) to run a marathon in every state before he gets too old, and 2) to form a pharmacists Road Runners Club. The only other pharmacist that he knows who is a serious runner is his friend Robert A. (Buzz) Kerr. Dr. Kerr is an Associate Professor of Clinical Pharmacy at the University of Maryland School of Pharmacy. He is a graduate of University of California (Davis) in 1966 and obtained his Pharm D from the University of California (San Francisco) UCSF in 1970. Buzz Kerr has run several marathons and also a triathalon.

CONGRATULATIONS TO:

MORRIS L. KESSLER, UofMD Pharmacy 1953 who helped save a man's life on January 19, 1985. On that day at Giant Pharmacy #166, Wilkens Blvd., Mr. Frank Klaschus suffered a massive heart attack while shopping in the store. Morris, who was the pharmacist on

duty, gave the victim cardiopulmonary resuscitation for almost 20 minutes before the paramedics from St. Agnes Hospital arrived. This potential tragedy had a happy ending as the patient was released from St. Agnes Hospital in mid-February and is doing quite well at home. St. Agnes Hospital presented the hero Kessler an honorary plaque which read "For acting in the spirit of a true neighbor by performing CPR on a fellow human being." Morris' name will also be inscribed on a dedication plaque which hangs permanently in the Coronary Care Unit of the hospital.

At the annual business meeting of the Alumni Association on May 7, 1985, the following members were voted into office:

Honorary President—Joe Bonvegna
President—Karen Demsky
President-Elect—Tom Williams
Vice President—Dave Knauer
Secretary—Lane Zangwill
Treasurer—Ron Sanford
Executive Committee—Mel Rubin, Chairman
Executive Committee Members include—Marty Mintz,
Cleveland Yee, Charles Sandler, Tom Patrick, Lee
Ahlstrom, Brian Sanderoff, Angelique Kariotis

CONGRATULATIONS TO:

JAMES CLOUGHERTY, P.D., who is now the District Manager-Pharmacies for the Murphy's Marts new drug store chain. Dr. Clougherty, 38, graduated from Duquesne University in 1970 and then proceeded to work as a pharmacist for Thrift Drugs until 1976. In 1976, James went to work for Murphy's Mart and has done quite well working up to his present position. As this is being written, two Murphy's Mart pharmacies, at Glen Burnie and Timonium, have been inspected and are due to open in May 1985. In July 1985, pharmacies are due to open in their Annapolis and Perring Plaza stores, and in October 1985, pharmacies also will open in the Pasadena and Randallstown stores. Dr. Clougherty, who is married and the father of two girls and one boy, also has the responsibility of the original five Murphy's Mart pharmacies in the Pittsburgh area.

PAUL R. HOLLY, P.D., who became Director of Pharmacy Operations for Valu Pharmacy in January 1985. Dr. Holly, who graduated from West Virginia University

in 1970, was a store manager with Peoples Drug Stores between 1970 and 1973. Then, between 1973 and 1985, Paul worked for the Veteran's Administration as first pharmacist and then chief pharmacist. During this period of time, he worked with the VA in four states which included Indiana, Ohio, Virginia, and finally, Maryland. Paul is married and the father of a 14 year daughter. He is also a member of the Maryland Pharmaceutical Association.

GARY A. STEWART, P.D., who became Director of Pharmacy at Maryland General Hospital in February 1985. Dr. Stewart is a 1978 graduate of University of Maryland Pharmacy School.

PHARMACY CHANGES—April 1985

The following are new pharmacies in Maryland:

Valu Pharmacy 4000 Seven Mile Lane Pikesville, MD 21208

Murphy's Mart Pharmacy #6831 6631 Ritchie Hwy. Glen Burnie, MD 21061

Total Home Nutrition Pharmacy 8925 McGaw Court, Suite 9 Columbia, MD 21045

Murphy's Mart Pharmacy #6823 2145 York Road Timonium, MD 21093

The following pharmacies have relocated:

Health Center Pharmacy, Inc. 1104 Healthway Lane Salisbury, MD 21801 (moved from Berlin, MD)

Rite Aid #691 3508 Eastern Avenue Baltimore, MD 21224 (moved from 3600 Eastern Ave.)

PHARMACY CHANGES—May 1985

The following is a new pharmacy in the State of Maryland:

Safeway Pharmacy #114 3268 Superior Lane Bowie, MD 20715

The following pharmacies have been closed:

Economy Drug Store 2200 E. Baltimore Street Baltimore, MD 21213 Asbill Pharmacy 42 W. Chesapeake Avenue Towson, MD 21204

Nattans Walther Pharmacy 3407 Hamilton Avenue Baltimore, MD 21214

The following pharmacy has a new address:

Rite Aid #353 408 N. Howard Street Baltimore, MD 21201 (formerly 501 N. Howard Street)

The following pharmacy has a new name and owner-ship:

AMI Doctors' Hospital of Prince George's County 8118 Good Luck Road Lanham, MD 20706 (formerly Doctors' Hospital)

RECENT PHARMACISTS DEATHS

Hans Morgenroth, P.D., age 63, died May 8, 1985. Graduated from the UofMD School of Pharmacy in 1947. Worked for various pharmacies in the Baltimore area.

Henry (Hank) W. Lawlor, P.D., age 61, died May 6, 1985. Graduated from George Washington University in 1955. Was the owner of County Drug Store in LaPlata, MD.

James L. Gundling, P.D., age 39, died April 1, 1985. Graduated from Columbia University, New York in 1969. Was the owner of Kent Pharmacy in Crisfield, MD.

A Trip to Salisbury, Maryland— April 18–19, 1985

Thrift Drug Store 7295—This is the first time I have met James Michael McGuire. Right away, he reminded me of a youthful Boog Powell of Oriole fame. Mike is tall, blonde, and has very pleasant ways. He informed me that he has just returned to work from a painful five week sick vacation in which he was operated on for two neuromas of the feet at St. Agnes Hospital in Baltimore City. Mike has recently bought a place for himself at Ocean Pines, which is near Ocean City. He is a UofMD Pharmacy graduate of 1983.

Ames Drug Store—Greeted by Jeffrey Scherr, UofMD Pharmacy 1978. Jeff and his wife, Joanne H., also a UofMD Pharmacy graduate 1978, have been in the

Salisbury area for a number of years both working for Ames Drug Store. A native of Baltimore, Dr. Scherr worked for Eli Lilly Drug Company as a detailman for several years after graduating from school. In his year-book, his name is printed Jeffrey *Brain* Scherr above his picture. It was quite a let down after he told me his real name was *Brian*.

Gordy's of Riverside Drive—While working in the store, a family tragedy occurred on the parking lot. A Fruitland, Maryland husband stabbed his wife in their car and all hell broke loose. Pharmacist Ellen Suber, with no hesitation at all rushed to the telephone and called for an ambulance and the police. Within minutes, both had arrived. Ellen, who is a graduate of Medical College of South Carolina in 1968, has been on the Maryland scene for some time now.

Medical Center Pharmacy—The pharmacist on duty was Philip M. Perry, UofMD Pharmacy 1974. He gave me some good news and some very sad news. The good news was since summer will be arriving soon, the Eastern Shore Pharmaceutical Association will have their annual picnic, cookout and softball game. In the softball game, the pharmacists, led by their star pitcher, Earl T. Smith of Crisfield will play the drug representatives. It is always a good time for all. The sad news was that James Gundling, pharmacist-owner of Kent Drug in Crisfield, recently passed away. Gundling, a 1969 graduate of Columbia University in New York, had been ill for a long period of time.

Drugfair #795—Mitchell A. Christian, UofMD Pharmacy 1966, has a black grayish beard similar to Santa Claus. He has been a movie fan for years. I remember him telling me that when he lived in Baltimore, he and a friend would leave one movie double feature and head straight for another movie house. He now owns over 100 of these old movies. One of the most popular is the original King Kong from 1928. Dr. Christian now is also very interested in computers since he recently bought one for his son. Now, between computers and movies, he really does not have much spare time.

Central Drugs—I did not get a chance to stop here, but while looking through the Salisbury telephone book, I saw a handsome, youthful Irv Kamanitz stare back at me.

The Dr. Paul Jablon Research Award in Pharmaceutics has been established at The University of Maryland, School of Pharmacy by Leon Jablon and the late Yetta Jablon, in memory of their son, a 1962 Pharmacy School graduate. Dr. Jablon who received his Ph.D. in Industrial Pharmacy from Purdue University, was an associate professor at the Albany College of Pharmacy at the time of his death. The \$10,000 Jablon Fund will be administered by the Pharmacy School Dean, and the first awardee for the 1985 Fall Semester will be rec-

ommended by Dr. Ralph Shangraw, Chairman of the Department of Pharmaceutics.

LOVE AND MARRIAGE AND CHILDREN

Eugene Balcerak, UofMD Pharmacy 1953 and wife announce the engagement of their daughter, Lisa Marie Balcerak, to Timothy Joseph Winter. It was not too long ago that we announced that their other daughter, Kathleen Teresa, graduated from the UofMD Pharmacy in 1983 and that she also was engaged.

Mr. and Mrs. Thomas P. Raimondi of Lutherville, Maryland, have announced the engagement of their daughter, Carol Theresa Raimondi to Dr. Dennis G. Foster, Jr. Mrs. Thomas Raimondi is the former Florence Elizabeth Moorehead, who graduated from the UofMD Pharmacy in 1953, and is now working at the Montebello Center Pharmacy in Baltimore.

Michael J. Sohmer, UofMD Pharmacy 1983, will soon be wed to Esther Benamor of Reisterstown. Mike's father is Herbert M. Sohmer, UofMD Pharmacy 1968, who used to own Fedder's Pharmacy in Dundalk.

Richard E. Myers, UofMD Pharmacy 1955 will wed Ann Harvey, R.N., who is on the staff of the Hopkins School of Hygiene and Public Health. Mr. Myers of the University Parkway Pharmacy in Baltimore will cease being single September 1, 1985.

From the School of Pharmacy:

- It was recently announced that pharmacist student Richard Daniel Hiller was married to Ina Barbara Hirsch.
- Pharmacist student Jamie Sue Klein will wed Mitchell Craig Levy in August 1985.

On April 1, 1985, Alexander Thomas Vitale was born. He is the son of Paul J. Vitale, UofMD Pharmacy 1978 and the grandson of Nathan Schwartz, UofMD Pharmacy 1943.

Janet Michael Abramowitz, UofMD Pharmacy 1981 and husband, Alan, recently became the parents of a bouncing baby boy on May 3, 1985. Mrs. Abramowitz has worked for Rite Aid Pharmacy and also part time for the Pharmacy at Shapiro's. They also have a young 2½ year old daughter, Sarah Chaya.



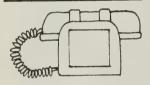


national scene

Space Shuttle Drug



Black Cancer Hotline



Generics on Rise



Antihypertensives Safe



Although the exact identity of the drug being synthesized aboard the U.S. space shuttle remains a secret, odds-on betting is that it is either urokinase (which dissolves blood clots) or interleukin. But whatever its identity, the Ortho Pharmaceutical Corporation is now beginning to test the drug in animals, and the company anticipates that it will be available for use in humans by 1988 or early 1989. A variety of materials are said to

It has generally been accepted for years that cancer rates among blacks are higher than those of the general population. New studies by the Federal government's Centers for Disease Control suggest that part of the problem of cancer within black communities may be related to lack of access to treatment, and, in addition, that blacks may not be sufficiently informed about cancer prevention. To help fill the information gap,

the National Cancer Institute is now

Some 40% of the nation's top-selling prescription drugs already have generic copies, and industry experts are expecting that generic-drug sales will comprise 7% of the prescription drug market this year and capture a full 25% of the market by 1990. One factor in their favor is that by the end of the decade, nearly all of the current 50 top-selling prescription drugs will be free from patent restrictions, open-

Long-term use of antihypertensive drugs to control high blood pressure is safe and effective, says the Federal government's National Institutes of Health following a national multiclinic study. In a five-year follow-up of 5,485 patients, no deaths were reported and less than 1% of participants required hospitalization. A total of 9.3% of participants had definite or probable side effects severe enough to discontinue drug treatment (8.3% of the

lend themselves to manufacture in space, where they can achieve a level of purity not otherwise possible. The reason is that, in space, the drug-separation process of electrophoresis works several hundred times more efficiently than on earth. The McDonnell Douglas Corporation has already announced it plans to produce commercial quantities of the still-secret drug, and that it will be used to treat several million patients.

targeting its Cancer Prevention Awareness Program specifically at black Americans. Pharmacists can do a valuable service for their black patients by letting them know of the Cancer Information Service toll-free number (1-800-4-CANCER) where they can get information on how to prevent the disease. Specific questions can also be answered by specially-trained experts, and written information on cancer-related topics can also be ordered.

ing the door for competition from generics. The use of generics will be pushed along by the Federal government's flat-rate Medicare reimbursement program, which is forcing hospitals to use lower-priced generics whenever available. Health maintenance organizations, unions, and Blue Cross are also beginning to require the use of generics whenever possible.

male participants had sexually related side effects which required discontinuation). An additional 23.4% had possible side effects that prompted an end to drug treatment. An interesting finding was that elderly patients appear to have a lower rate of adverse reactions to drug treatment than do younger patients, with the older individuals showing less incidence of orthostatic hypertension, depression, lethargy, and drowsiness.



Northeast Symposium on Women in Pharmacy

November 1 - 3, 1985 Summit Hotel — Hartford, Ct.

PROGRAM

Judith Cardoni, Chairman

FRIDAY 2:00 - 6:00 p.m. Registration 7:00 - 8:00 p.m. Cash Bar, Hot and Cold Hors D'Oeuvres 8:00 - 10:00 p.m. Imaging Success Angele C. D'Angelo, M.S. Assistant Dean, St. Johns University College of Pharmacy and Allied Health SATURDAY 8:00 - 9:00 a.m. Coffee and Croissants 8:00 - 12:00 noon Registration 9:00 - 9:45 a.m. Keynote Address The Increasing Role of Women in Pharmacy Marvin D. Shepherd Ph.D. College of Pharmacy, Univ. of Texas at Austin 9:45 - 11:00 a.m. Professional Employment Skills Barry Bleidt, Ph.D. Northeastern University, College of Pharmacy and Allied Health Professions 11:00 - 11:30 a.m. Break 11:30 a.m. -Reactor Panel Barry Bleidt, Ph.D., Moderator 12:30 - 2:00 p.m. Lunch 2:00 - 5:00 p.m. Workshops Ethics and Pharmacy_ Joseph M. Healy, Jr., J.D. Univ. of Conn. School of Medicine Time and Stress Manager_ Edward F. Iwanicki, Ph.D. Assoc. Dean, School of Education Univ. of Connecticut Current Pharmacy Issues_ Gloria Sabatini, B.S. Health and Public Affairs Consultant Professional & Political Involvement_ _Pauline Montgomery, B.S. Pharmacist, Hughesville, PA Communication Skills_ Amy K. Lezberg, Ph.D. Assoc. Dean, Mass. College of Pharmacy and Allied Health Sciences Personal Goal Setting_ _Claire M. Nolin, B.S., M.A. Professional Consultant 5:00 - 6:30 p.m. Wine and Cheese SUNDAY -

The Symposium will bring together pharmacists from throughout the country to discuss issues affecting women in pharmacy. The goal of the Symposium is to build skills in imaging, communications, stress/time management and financial planning, and to increase professional involvement. Participants will learn the tools to network effectively, become aware of current pharmacy issues and have a better understanding of ways to attain personal and professional goals. The Symposium is sponsored by the Connecticut Pharmaceutical Association in cooperation with the Connecticut Society of Hospital Pharmacists and the UConn School of Pharmacy.



Dr. Marvin Shepherd

Keynote Speaker, Dr. Shepherd, is Assistant Professor, College of Pharmacy, University of Texas at Austin, teaching graduate and undergraduate courses in pharmacy management, marketing, research design and statistics. He is a graduate of Michigan Technological Univ. (B.S. Biology); Ferris State College (B.S. Pharm.); Univ. of Rhode Island (M.S.); Purdue Univ. (Ph.D.).

For registration information contact: Daniel C. Leone, P.D., Coordinator, Conn. Pharmaceutical Association, 943 Silas Deane, Wethersfield, CT 06109. (203) 563-4619

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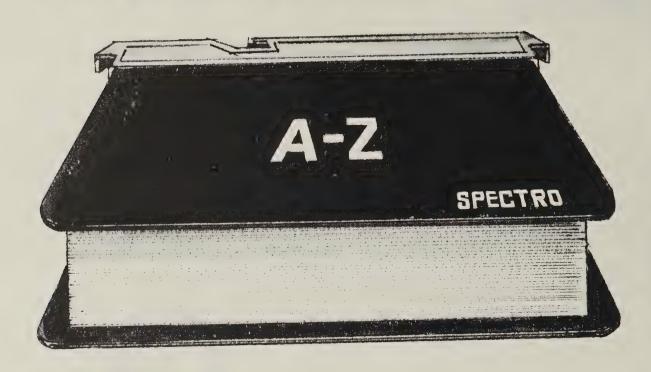
11:30 a.m. - Wrap Up

9:00 - 10:00 a.m. Buffet Breakfast

10:00 - 11:30 a.m. Personal Financial Planning Jane E. Green

> The Future of Pharmacy Marvin D. Shepherd

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Paul Freiman, Secretary of the Maryland Board of Pharmacy delivers the report of the Board as required by State Law to the Annual Convention of the MPhA. A reprint of the Board's report is provided on page 14



Betty Sanford received "Pharmacists Mate" Award from Geigy representative Dave Holmes at the Annual Convention Banquet.



The Crab Feast at the Annual Convention again attracted record crowds, most of whom stayed for the square dancing which followed.



In-coming President Madeline Feinberg presented out-going President Ronald Sanford with the Past President's Award shortly after the change in leadership.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

FOOD/DRUG INTERACTIONS:

Many factors can be involved in reducing the effectiveness of a drug product including the interaction of the drug with components found in foods. Food may modify the time needed for gastric emptying, and thus allow for interactions to take place in the stomach. Food may delay the absorption of certain drugs, e.g. the second generation sulfonylureas and some antibiotics, so these agents should be administered either one hour before a meal or two hours afterward. Calcium and other divalent and trivalent cations are known to form insoluble salts with some drugs, e.g. tetracycline. The physical presence of food reduces the bioavailability of atenolol (Tenormin), captopril (Capoten), rifampin and INH. Ingestion of hydrocarbon containing materials, e.g. charcoal broiled steaks, or smoking of cigarettes, seems to enhance the metabolism of a drug product as it crosses from the lumen of the intestine to the portal circulation. Nitrofurantoin and hydrochlorothiazide, on the other hand, are lipid soluble agents and seem to be absorbed better in the presence of food. Br Med J, Vol. 289, #6452, p. 1093, 1984.

KETOACIDOSIS:

Diabetic patients are occasionally treated with intravenous bicarbonate solutions to help reverse the ketoacidosis associated with severe hyperglycemia. Acidosis can cause a decrease in cardiac output and peripheral resistance which may lead to the production of profound hypotension. Arrhythmias are also more likely to appear during times of acidosis. Controlled experiments indicate that the use of bicarbonate in patients with diabetic keotacidosis serves no purpose unless metabolic conditions are significantly altered. *Br Med J*, Vol. 289, #6451, p. 1035, 1984.

ENDOGENOUS DIGOXIN:

Patients who had never received digoxin or other cardiac glycosides have been shown to have a substance in their plasma which reacts with the antibodies used to made digoxin serum determinations. These endogenous digoxin-like substances, (EDLS), are present to such an extent in preterm infants that they may significantly distort actual plasma levels of the glycoside and lead to inaccurate dosing of the glycoside. In preterm infants or others found to have EDSL in their plasma, it may be necessary to obtain a level prior to therapy and then calculate the dose of the glycoside based on results from this assay. Additionally, it will be necessary to develop an assay which would be more specific for the digoxin molecule. *Clin Pharmacol Ther*, Vol. 36, #6, p. 759, 1984.

CLONIDINE:

Diuretics, analgesics, and tranquilizers have been used to treat premenstrual tension syndrome. A limited number of uncontrolled studies have suggested that clonidine (Catapres) may have a beneficial role in the treatment of this condition. Double-blind, placebo controlled studies are needed before any definite recommendations can be made concerning the use of this antihypertensive agent in the treatment of premenstrual tension snydrome. *J Clin Pharmacol*, Vol. 24, #10, p. 463, 1984.

OSTEOPOROSIS AND ANOREXIA NERVOSA:

Women who were characterized as having anorexia nervosa were studied to determine what the effect of a reduced calcium intake might have on bone density. It was noted that vitamin D and parathyroid hormone activity were generally within normal ranges, but some women experienced a reduction in bone density. When factors such as age, weight, duration of illness or serum estrogen levels were accounted for, it appears that the reduction in bone density was greatest in sedentary women. Those anorexic women who obtained a high level of physical activity had bone densities which were similar to both active and sedentary controls. *N Engl J Med*, Vol. 311, #25, p. 1601, 1984.

NITROGLYCERIN:

Nitroglycerin is used in various types of formulations in order to achieve safety and therapeutic efficacy. Topically applied nitroglycerin has been found to undergo rapid metabolism by the normal staphylococcal flora of the skin. This reduction in drug concentration may lead to reduced efficacy of topical nitroglycerin preparations. All drugs administered topically should be examined to determine if any component of the normal dermatological flora might be capable of causing the activity of the product to be altered. *J Pharm Pharmacol*, Vol. 36, Supplement, p. 619, 1984.

RENAL DOPAMINERGIC ACTIVITY:

The dopamine-1 receptor in the kidney is thought to have some role in the regulation of normal blood pressure. A selective dopaminergic-1 stimulant, fenoldopam, was found to reduce pressure in patients with essential hypertension. The authors of this article suggest that reduced dopaminergic activity at the renal dopaminergic-1 (DA-1) receptor may contribute to the etiology and perpetuation of essential hypertension. J Clin Invest, Vol. 74, #6, p. 2198, 1984.

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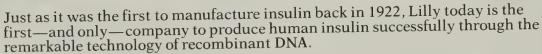
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The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Cromwell Bridge Road Beltway Exit No. 29. For further information contact President Frank Block (phone: 358-2743). This organization has several veteran pharmacists available for part-time employment.

Baltimore City College Alumni

The Baltimore City College Alumni Association is alive and well and working vigorously to support the old "Castle on the Hill." All B.C.C. Alumni are urged to support their old school with their membership. An application may be obtained by phoning 484-5262 evenings.

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Jon D. Johnson, owner of Clinton Pharmacy in Clinton, Maryland, won first prize in the first Juvenile Diabetes Foundation National Telethon Sweepstakes and an expense-paid weekend trip for two to attend the recent Telethon held in Atlantic City, New Jersey.



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THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

October, 1985 VOL. 61 NO. 10





Looking Into The Future
SPECIAL ISSUE

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET BALTIMORE MARYLAND 21201 TELEPHONE 301/727-0746

OCTOBER, 1985

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Looking Into The Future

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Have you ever wondered what pharmacy practice might be like in the twenty first century? What will our drugs be like, or the practice of medicine, or our entire health care delivery system just 25 years from now?

Fifty leaders from pharmacy professional and trade organizations, industry, government and the private sector were invited to explore developments likely to take place in our profession at "Pharmacy in the 21st Century", a conference held at Project Hope Center in Millwood, Virginia, March 1984. There were many forecasts, some optomistic, some not, depending on your perspectives and expectations. One finding for certain, participants agreed that pharmacy practice will be different!

With permission of the American Association of Colleges of Pharmacy, we have reprinted segments of the Executive Summary of this conference to give you a "taste" of the possible future. As you read these exerpts, you will probably recognize that in some situations, the future is now.

Indeed, we as practitioners are called on to make decisions today based on changes which we never anticipated would happen even five years ago. To facilitate the pharmacy practitioner's approach to changes, both current and anticipated, the Virginia Pharmaceutical Association and the Maryland Pharmaceutical Association will co-sponsor a regional (8 state) meeting of the "grassroots practitioners" to address some of the major findings of the Conference. Our objectives will be to stimulate a pro-active approach to future challenges, to generate new thinking and to encourage participants to begin positive planning for the future.

Stay tuned . . .

(See the article beginning on page 10)

Madeline Feinberg
1985-86 PRESIDENT

SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 9

Advising Consumers on Common Ear Disorders

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
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Professor of Clinical Pharmacy
University of Cincinnati
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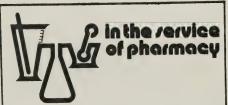
Goals

The goals of this lesson are to:

- describe the etiology and treatment of common ear disorders;
- explain how to advise patients on self-medication of these disorders.

Objectives

At the completion of this lesson, the successful participants will be able to:



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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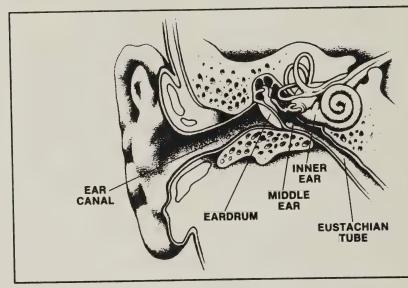


Figure 1. The ear.

- show an understanding of how common ear disorders are contracted;
- 2. recognize effective OTC agents for these disorders;
- explain the proper technique for instilling otic products;
- 4. decide when the patient should be referred to a physician.

Disorders affecting the ear are common. Pharmacists are routinely asked to recommend treatment for earaches, impacted earwax, "running ear," congested ears, or itching and irritation associated with infection.

During the fall and winter months, many prescriptions for antibiotics, decongestants and analgesics are written to treat otitis media (middle ear infection), especially in children. Otitis media is one of the most common medical disorders of children. However, there are no OTC products that effectively treat otitis media.

Self treatment of otic disorders is generally restricted to conditions of the outer ear. One exception is barotitis, the painful sensation that originates in the middle ear that is caused when an individual descends too quickly from a high altitude, such in an airplane.

Otic pain is a general symptouthat may result from a variety of conditions. It may also originate elements where and be referred to the ear is lowing injury or trauma to the jaw nasopharynx, tongue, tonsils or panasal sinus area. Loose fitting detures, eruption of molar teeth, dental infection may cause paround the ears. Poorly fitting plugs or hearing aids may likew cause localized discomfort that we interpreted as pain.

The Ear

The ear is divided into three s tions: external, middle, and inter (Figure 1). The external (outer) includes the auricle (pinna) and canal. Its function is to receive a transmit sounds into the middle of

The skin and underlying subcineous layer lining the ear canathinner than elsewhere on the bc The skin is also tightly stretch Therefore, the slightest inflamition will be interpreted as hav greater intensity than a quantitation.

ly similar inflammatory reaction elsewhere on the body. Pain originating in the tissue anywhere along the external ear may indeed be aggravating and uncomfortable. However, its intensity will not always accurately describe the actual extent or severity of the underlying condition.

The external ear is separated from the middle ear by the eardrum (tympanic membrane). This thin membrane is about 9 mm in diameter about half the width of a dime). The eardrum is considered to be part of he external ear because its outernost layer is continuous with the epthelium that lines the ear canal. It protects the middle ear from contamnation by foreign material. It also ids in transmission of sound into he middle ear by vibrating as sound vaves reach it.

The middle ear is an air-filled cavty connected directly to the nasoharynx by the eustachian tube. The ustachian tube is normally colapsed, but opens during swallowng, chewing, yawning and moving ne jaw. This allows for equalization f air pressure on both sides of the ardrum to prevent damage to bones f the middle ear structures. The iddle ear contains the ossicles, carlaginous structures of sound transnission. When moved by the earrum, these ossicles - the malleus nammer), incus (anvil) and the staes (stirrup) — amplify and transmit ound waves into the inner ear.

The inner ear consists of the cocha, a snail-shaped spiral tube which the essential organ of hearing, and the vestibular apparatus. The latter ructure is responsible for mainteance of balance and equilibrium.

ommon Ear Disorders

xcessive Earwax

Approximately two-thousand seceous glands line the outer one-ird portion of each ear canal. lese glands produce a highly visus, waxy, repellent substance flown as cerumen, or earwax. Early is colorless when secreted, but rns brown as it mixes with exfoligid (shed) skin, dirt, and debris om within the ear canal. This town color and reported acrid odor parently give the substance its discreeable appearance.

Cerumen consists of fats, fatty acids, water, pigments, and several other yet unidentified substances. Its consistency, (hardness), color, and quantity are unrelated to an individual's age or sex. Consistency is determined by the water content. Color is dependent on the amount of dirt and debris present.

Cerumen serves several important functions. It lubricates the lining of the ear canal and helps remove foreign substances that enter the ear, to protect it from damage. It also possesses mild bactericidal and fungicidal actions.

Cerumen is normally expelled from the ears unnoticed in tiny spheres. This movement is aided by movement of the jaw during chewing and talking. Its removal is automatic and ordinarily does not need any assistance. In fact, mechanical removal by inserting hairpins, matches, and similar objects is one of the major causes of trauma and injury to the ear canal. Studies show that most Americans believe earwax should be mechanically removed.

This removal is occasionally impeded because the individual's ear canal is too narrow. Excessive hair (tragal hair) within the ear canal, or long, coarse hair (especially in older persons), may trap earwax to enhance the retention of a hardened mass of cerumen. On other (rare) occasions, sebaceous secretions may be excessive and allow accumulation of highly viscous material that resists movement. Insufficient chewing and jaw movement are other causes.

The "evils" of earwax and the public's insistence to get rid of it have no doubt been strengthened over the years by articles and advertising claims. It has been suggested that the presence of earwax implies poor hygiene, that deafness is caused by earwax accumulation, and that hearing loss associated with old age can be reversed by cleaning out the ears.

In a study, over one-hundred persons were asked the leading question (thereby expressing approval), "How do you clean your ears out?" More than half of the respondents indicated they used matches wrapped in cotton, and two used the striking end without cotton. Seven said they preferred hair pins. Another four used cotton-tipped applicators.

Carefully performed, such items may help to remove fluid cerumen.

But they do not remove dry cerumen. Various studies have, in fact, reported that as many as 75 to 80 percent of all external otitis conditions are caused by individuals using cotton-tipped applicators and other probing objects to clear the ears of earwax. Trauma to the ear canal with epithelial atrophy can be caused by any instrument, even cotton-tipped applicators, placed into the ear canal. Many times these objects push the wax deep into the ear and impact it even more. Its natural removal is thus made even more difficult.

Earwax Softening Agents. As the name implies, these agents soften and loosen earwax. They are available for purchase without prescriptions. These drug products are not the same as cerumenolytics (e.g., triethanolamine polypeptide oleate condensate - Cerumenex®) which actually dissolve earwax. They require prescriptions.

Common agents used for softening earwax include olive oil (sweet oil), light mineral oil (baby oil), 3% hydrogen peroxide solution diluted by half with warm water, glycerin, and carbamide peroxide. Hydrogen peroxide is satisfactory for occasional application, but should not be used routinely. If it is left in the ear, it can cause maceration of epithelial tissue lining the ear canal, which then predisposes it to infection. Representative OTC products for softening earwax are listed in Table 1.

Carbamide Peroxide (urea hydrogen peroxide). This was the only earwax softening agent that an FDA/OTC advisory panel found to be safe and effective for OTC sale. Carbamide peroxide in anhydrous glycerin has been used as a topical antiseptic for treatment of inflammatory ear conditions since 1946 because it is safe, non-irritating, and non-allergenic. To date, there have been no reports of adverse effects associated with its use.

When it comes into contact with the tissue enzyme catalase, carbamide peroxide releases oxygen. The mechanical action of effervescence from this bubbling oxygen loosens tissue debris and wax, and aids in cleansing the ear canal. There is no proven antimicrobial action that results from this oxygen release.

The FDA advisory panel believed that carbamide peroxide has estab-

TABLE 1
Representative OTC Products for Softening Earwax

Softening Earwax				
Product	Manufacturer	Ingredients		
Auro Ear Drops	Commerce	Carbamide peroxide 6.5%, in propylene glycol		
Aurocaine Ear Drops	Republic	Carbamide, glycerin, and propylene glycol		
Debrox Drops	Marion	Carbamide peroxide 6.5%, in anhydrous glycerin		
E-R-O Ear Drops	Scherer	Glycerin 95%, in propylene glycol		
Kerid Ear Drops	Blair	Glycerin 30%, urea 0.1% in propylene glycol		
Mollifene Ear Drops	Pfeiffer	Camphor, cajuput oil, eucalyptus oil, thyme oil, in glycerin		
Murine Ear Drops	Abbott	Carbamide peroxide 6.5%, in anhydrous		

lished efficacy. In one study, twentysix patients with bilateral excessive or impacted earwax received ten drops of 6.5% carbamide peroxide in anhydrous glycerin in the ears twice daily (morning and bedtime) for six days. This was followed by irrigating the ear canals with lukewarm water twice daily on days five and six. A physician examined the ears on day seven. Complete removal of wax was exhibited in twenty-two patients. Two others required an additional irrigation, which was met with complete success. The remaining two required a second course of treatment at which time the procedure was determined to be successful.

glycerin

In another study, fifty-seven patients with physician-documented impacted earwax used carbamide peroxide in anhydrous glycerin for three days. This was followed by irrigation with warm water. The treatment was successful in all cases.

The proper procedure for administering ear drops is to tilt the head sideways (affected ear upwards) and place 5 to 10 drops into the ear. The applicator tip should not enter the ear canal or touch any part of the ear. The drops should remain in the ear for several minutes by keeping the head tilted or by inserting cotton. If cotton is used, it should be inserted gently and not packed too far into the ear canal.

Irrigation is not usually necessary when carbamide peroxide products are used correctly. As simple as the procedure sounds, not everyone can syringe his own ears. Syringing requires considerable caution and dexterity. The FDA advisory panel believed that placing an irrigating syringe in the ear should not be done more often than absolutely necessary. Therefore, it suggested that directions for use of carbamide peroxide be expanded to state: "Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb syringe."

Earwax that remains after four days of self-therapy could signal a serious medical problem and a physician should be consulted. Thus, there is an additional warning: "Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor."

Products containing carbamide peroxide are safe for relieving symptoms of fullness due to accumulated, but not impacted, earwax. All other symptoms such as earache or itching, draining, hearing impairment due to impacted earwax, ear noises (tinnitus) and dizziness may suggest a more serious disease which requires a physician's attention. To remove impacted earwax, a cerumenolytic agent (none available OTC) or intervention by a physician may be required.

Glycerin. This old-time remedy has been used alone and in combination with other agents for more than a century as a softening agent for earwax. However, there have never been any well controlled studies to establish its effectiveness as a topical earwax softening agent. The FDA/OTC advisory panel which reviewed it suggested that the lack of scientifi-

cally valid trials for glycerin is more than offset by its century of wide spread clinical use and marketin experience. It is also safe and nor sensitizing when used on abrade skin. The panel, therefore, recon mended that glycerin be considere a safe and effective earwax softening agent.

However, FDA disagreed with thi The agency stated that "...the existing evidence are not adequate support the effectiveness of glyceri as an earwax removal aid." Because glycerin still needs additional evaluation before it can be used alone soften earwax, FDA placed it in the "needs more study" category. Anhy drous glycerin can continue to bused as a vehicle for carbamide peroxide.

Boils

Boils (furuncles) are localized i fections of hair follicles. They a usually caused by Staphylococcaureus and are self-limiting. Boi commonly occur on the auricle within the ear canal beginning as i flamed, red papules (hardened sol mass), but soon pustules appear their place. Over the next sever days to two weeks, these gradual enlarge and open spontaneously, I leasing their yellowish contents.

Boils may be extremely painf due to the reasons explained earli in this lesson. Boils located with the ear canal will cause pain that exacerbated by chewing.

A boil should not be squeezed pinched open. This may cause the infection to spread by forcing pus i to adjacent tissue or even into the blood. Warm compresses can be a plied several times daily to haste the boil coming to a head. Once the occurs, the discharged fluid shou be carefully removed, and the su rounding area cleansed. While top cal antibiotics will not effective treat an infection, an antibiotic oir ment can be applied to help preve invasion by secondary infective (ganisms. This should be applied a er the boil has erupted.

Fungal Infections

Fungal infections (otomycoses) as more often encountered by persorresiding in warm, moist climate than those living in colder climate.

Candida and Aspergillus species are he usual causes.

Patients with fungal infections vill report generalized and persistent itching, irritation, and a sense of ullness in the ear. Pain is usually abent except in severe infections. If resent, it will be increased by chewng or yawning. The exudate from he infection is colorless and, when xcessive, may block the ear canal.

Diabetics and persons taking road spectrum antibiotics are more rone to otic fungal infections than thers. Diabetics are more susceptile because their circulation to the rea is generally poor, and antibiotics may suppress the normal bacteriflora. This predisposes the indiidual to superinfection by fungal rganisms.

oreign Objects in the Ear

Young children often place small pjects or bits of food into their ears. nysicians regularly report removing peas and beans, seeds, rocks and aper wads. Foreign objects in their are often relatively painless. The only clue to their presence may be a mild's persistent pulling on the aucle, or impeded hearing. Insects any also enter the ear, becoming apped within the canal or imbedied in earwax.

Unless the foreign object can be sily grasped with the fingers, no tempt should be made to remove it. his is best left to a physician. Income within the ear canal can often coaxed out by shining a light fam in the ear. If this doesn't work, he ear cavity can be filled with minual or olive oil to drown the invader, and syringed with water 5 to 10 minus later to remove the insect.

rotitis (Baro-otitis)

This is a condition encountered by sons descending from high alties. It is more common when perts have inflamed sinuses or contion resulting from an allergy or d cold.

tecall that the eustachian tube is mally closed. As the individual cends to a lower altitude (greater ometric pressure), the tube opens llow for pressure within the midear to equalize the pressure outs the ear. However, at times, the

tube fails to respond. This results in a negative pressure within the middle ear. The eardrum retracts, causing severe pain.

The condition is usually bilateral, although it may occur in only one ear. It is more prevalent during periods of congestion when mucus may cohesively bond the eustachian tube together, or physically occlude the tube's lumen. The result is that, as the individual descends, pressure within the middle ear increases more and more. This causes intense pain that may be felt along the entire side of the face and radiate across the back of the head and down the neck.

The condition is often relieved by chewing, yawning, or rotating the jaw. As pain relief is experienced, holding the jaw in that exact position for a few seconds usually allows for complete pressure equalization. Holding the mouth and nose shut while trying to blow outward also helps.

Persons who must fly while they are severely congested can be advised to take a systemic decongestant. This should ideally be started the day before the flight. A topical nasal decongestant instilled 10 to 15 minutes before descent may reduce the severity of discomfort.

If the discomfort persists after these measures have been employed, an OTC analgesic may be helpful to reduce pain. Warm compresses placed over the ear, and sides and back of the neck often help the eustachian tubes open.

Drainage/Discharge

A discharge from the ear may be watery (serous), bloody, or contain pus (purulent). Any trauma to the ear or head may cause bleeding. An infection may cause exudation of a pus-laden fluid. Self treatment of otic drainage from any cause is not appropriate. A physician should be contacted as soon as possible.

Swimmer's Ear

Swimmer's ear (acute edematous otitis externa, acute otitis media, "hot weather ear") is discussed more thoroughly in another lesson in this SCOPE series entitled, "Advising Consumers on Swimmer's Ear." It is briefly described here to make this month's lesson complete.

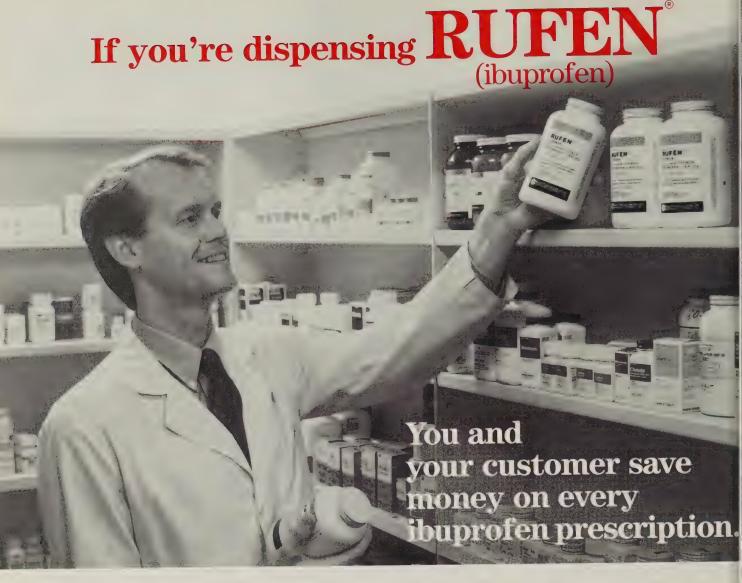
Swimmer's ear occurs predominantly during the hot summer months. It may also appear following frequent showering, or immersion in bath water, and is more common in individuals residing in hot, humid climates.

The condition may appear whenever extraneous moisture enters the ear canal. Earwax softens and swells. If foreign debris or bacteria enter the ear canal at this point and become trapped in this waxy mass, and the individual scratches or rubs the ear, damage to the ear canal with localized infection may result. The outcome is intense itching and pain in the ear canal.

Swimmer's ear is treated with antibiotics and anti-inflammatory otic preparations under a physician's direction. It can be effectively prevented, however, by remedies intended for self-treatment that dry the ear canal. Such items include extemporaneously prepared solutions of acetic acid 2 to 5% in alcohol, propylene glycol or anhydrous glycerin. A variety of OTC proprietary products is also available.

Overview

Most disorders of the ear are mild and do not pose major problems. However, even mild pain and itching can be symptoms of serious disorders. To continue to treat these symptoms without seeking their cause may lead to irreversible harm to the ear, or worsening of the primary condition. Any symptom that persists beyond two days or worsens even though it is being self-treated should be referred to a physician. It is also important for the pharmacist to distinguish between conditions where OTC treatment is indicated and those where an OTC item should be avoided and the patient referred to a physician. 🥡



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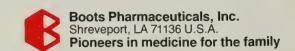
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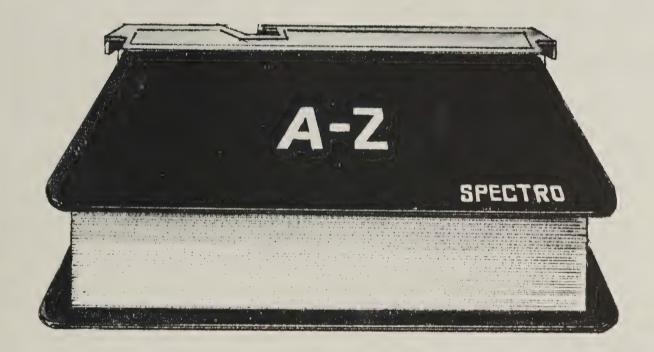
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Looking Into The Future

Pharmacy in the 21st Century

A Strategic Planning Conference:

The Pharmacy Profession in Cooperation with the Institute for Alternative Futures and the Project HOPE Institute for Health Policy and American Association of Colleges of Pharmacy

Executive Summary: "Pharmacy in the 21st Century" Conference

Drugs—and the way we obtain them and use them—will be far different in the year 2010 than they are now:

- Increased consumer interest in self-medication and health promotion will lead to a wide variety of wellness-enhancing substances that are not available today.
- Traditional medicines as we know them will be readily available without a prescription; their safety and efficacy will have been proven by decades of use.
- A new trend will be high-technology therapies based on research breakthroughs now occurring. These new pharmaceuticals will give rise to treatments for cancer, inherited diseases, and breakdowns of the immune systems, such as AIDS. Some of these treatments will be tailored to an individual patient's needs by the pharmacist at the treatment site.
- Many drugs will be provided in more targeted and more controlled delivery systems.

These are some of the predictions for the year 2010 that emerged from a conference considering the future of pharmacy and its role in health care. The conference, called "Pharmacy in the 21st Century," was held at the Project HOPE Health Sciences Education Center in Millwood, Virginia, March 25–28, 1984. Fourteen health care thought-leaders presented individual papers on various aspects of developments likely to take place in the next 25 years. These experts developed a range of forecasts of things to come for pharmacy, based on a set of scenarios presented by the Institute for Alternative Futures.

More than 50 representatives from seven professional pharmacy and trade associations, nine pharmaceutical manufacturers, and other sectors of the health care system discussed the various elements in the four scenarios and how they would affect pharmacy's future.

At a final session, conference participants expressed their opinions on the most likely shape of the future and the most likely changes in various aspects of pharmacy practice in that future.

Background and Rationale of the Conference

The conference on the future of pharmacy was particularly important because of the dramatic changes in the profession since World War II. Pharmacists' traditional roles, such as dosage from preparation, have been preempted by manufacturers, leaving the pharmacist without a unifying thrust for the discipline. Pharmacy education has changed its focus from the drug product to drug therapy of the patient, teaching pharmacists to be experts in the safe and effective use of medications and how to put this knowledge into practice.

As a result, in some settings pharmacists seem isolated from the prescribers and even from patients. At the same time, newer, non-traditional roles for pharmacists are emerging.

The mission of the conference was to consider such issues as:

- the nature and quantity of health care and pharmacy services sought in the year 2010;
- the total drug volume and classes of drugs and pharmacy functions and practice locations in the 21st century, as well as the relative proportions of prescription and OTC drugs;
- pharmacy personnel needs, including the total number and types of pharmacists and how pharmacy education must respond to prepare students for their changing roles.

One clear conclusion from the meeting was that pharmacy's world will be different in the 21st century. But that prediction is not enough for effective planning. Three additional questions were raised at the meeting and answered as well as current information permits:

- What is the likely range of possible environments in which pharmacy might find itself at the beginning of the next century?
- How might these different environments affect the practice of pharmacy? and
- Among alternative futures, which outcomes are most likely to occur?

Alternative Futures I: Society

The society in which health care services are delivered will alter greatly by the next century. Some trends were sketched by keynote speaker Rick Carlson, an author and health care expert. These trends included a longer period of life free from disabling disease, the "compression of morbidity" phenomenon; increased use of computers and other electronic devices for communication; greater consumer competence; more eco-

nomic competition among hospitals, which will "take away the issue of admitting privileges from doctors;" a shift from infectious diseases to chronic diseases, many caused by environnmental toxins; and a heightened appreciation of biochemical individuality.

One important question for health care workers considering their future, Carlson said, is, "What profession or business are we in?" In the case of pharmacy, a relevant distinction is between health care delivery and chemistry. If most functions involving dispensing therapeutic chemicals are automated or obsolete in the next century, will there still be a pharmacy profession?

Other social trends were outlined by psychologist Dr. Ken Dychtwald, who placed major emphasis on the continued increase in the number of aged persons in future societies. Predictions about the impact of this change on drug use must consider the possibility that the old persons of the future will not have chronic disease to the extent that we see today. Dychtwald also foresees increasing self-management by patients, who may "use doctors as advisers and pharmacists as information sources."

Dr. Clement Bezold presented a broad-based framework for examining the future, under the rubric of possible future scenarios. "Scenarios are a way of making sense out of a blizzard of data and conflicting predictions." Bezold said. In these coherent models, he outlined four scenarios that incorporated a range of possible changes, including the forecasts of futurists such as Alvin Toffler in *The Third Wave*, John Naisbitt in *Megatrends*, and others.

The model scenarios can be characterized simply under the following headings:

- Continued growth: The kinds of things that made America great prevail.
- Decline and stagnation: Management and technology fail; the economy stagnates in cycles.
- Disciplined society: Social regimentation overcomes economic stress.
- *Transformation:* Altered values lead people to use technology for more humanistic ends.

Health care changes in these scenarios range from elimination and control of many diseases under the continued growth assumption, to the stagnation of the health care system as well as the economy in the decline and stagnation scenario, to forced healthful habits in the disciplined society, to an eclectic mixture of individualized technology and greater dependence on wellness and spiritualism in the transformation scenario. It was these scenarios, enhanced by the other presentations, which the conference participants used to explore the environment for pharmacy in the next century.

Other forces are also shaping the future. Ethicist Dr. Dan Callahan, Hastings Center Director, noted recent major changes in our value systems. One primary trend has been the transition from an individualistic society to a more restrained culture, with greater emphasis on

character and virtue. The most powerful moral principle in the medical arena is "We cannot have everything we want," Callahan said. This implies the obligation to make choices.

Dr. Lawrence Lutz of the University of Utah Medical Center provided insights into the role of computers in the medical-care system of the future. He predicted that soon computers will reason inductively. But as for the details, Lutz said, "No one knows what that will be like. We're all riding horses and we know that autos will come along, but we don't know what they will be like."

Future medical computers will probably contain not only databases—collections of facts—but also knowledge bases—rules for drawing selected inferences from information and data inputs provided on an ad hoc basis. To the extent that these knowledge bases contain what doctors now try to remember, computers will take over some human functions. But, Lutz said, patients will probably continue to look for personal care as they do now.

Physicians will use the computer increasingly to assist them in difficult diagnoses. In turn, patients may use computers more for self-care, including drug use, while pharmacists may have a role in monitoring patient status.

Alternative Futures II: The Marketplace

General economic determinants of the future health care marketplace were described by Drs. Jack Meyer and Gail Wilensky. Meyer, Director of the Center for Health Policy Research at the American Enterprise Institute, warned that the theme for the future cost of health care is, "Hold on to your wallets. It's no accident that we have one of the most expensive health care systems in the world." Some factors contributing to that high cost are: expensive technology—"Most of what medicine does confers some benefit, but it is costly;" an increasing number of older people; and "blank-check" reimbursement policies. Changes in the last factor are coming, but will not overcome the pressures of the first two. One effect of payment reforms: greater emphasis on drugs as substitutes for more expensive technologies.

Project HOPE's Wilensky asserted that current U.S. social policy is "very implicit," while Medicare is a political compromise and Medicaid is limited by expediency. And one major federal program in the health care field is not even acknowledged as such: the tax policy that exempts the employer's contribution to health care from the employee's taxable benefits. Health policy will change, said Wilensky, although it is not clear whether the main impetus will come from the government or from corporations. Whatever the case, those changes will most likely mandate that individuals become more prudent buyers of care.

Wilensky rejected the decline and stagnation and

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John Piecoro, Jr., Pharm. D. Clinical Pharmacist University of Kentucky Lexington, Kentucky

Seated Left to Right:

Charles Lippert, R.Ph. Community Pharmacist Zeeland, Michigan Reed Rosling, R.Ph. Vice President, Hospital Sales Bergen Brunswig Drug Co. Orange, California

William Thien, R.Ph. Director, Health Services & Pharmacy Operations Walgreen Drug Stores Deerfield, Illinois Carl Lyons, R.Ph. Institutional Pharmacist Tulsa, Oklahoma

John Kogut, R.Ph. Vice President Fay's Drug Company Liverpool, New York Larry Braden, R.Ph. Executive Vice President Georgia Pharmaceutical Association Atlanta, Georgia

Lonnie Hollingsworth, R.Ph. Community Pharmacist Lubbock, Texas Marily Rhudy, R.Ph. Community Pharmacist Topeka, Kansas

Bernard Mehl, R.Ph. Director of Pharmacy Mount Sinai Hospital New York, New York

Not pictured: John Colaizzi, Ph.D., Dean, College of Pharmacy, Rutgers University, Piscataway, New Jersey

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transformation scenarios, the former because it is "extraordinarily unlikely" that the U.S. will not have continued growth for the next 25 years, and the latter "because of what it implies about changing patterns of motivation and behavior."

The hospital perspective was provided by Dr. W. Keith Weikel, Group Vice President of American Medical International. The hospital environment will also change, he noted. These changes can be predicted. since "anything we will see in the year 2000 we've already seen start today." He saw as the main trends a static or maturing medical industry and increasing dependence on alternative healthcare and wellness approaches, consistent with the transformational scenario. Hospitals will become vertically integrated health care corporations with services spread throughout the community. The hospital as we know it will be mostly a critical care unit and "a place for the undiagnosed to die." Because of increased competition, "marketing will demystify medical care and create a more active and informed consumer."

One crucial issue will be who controls access to the patient. As competition heats up, "Doctors will fight to maintain their income levels," Weikel said. Doctors will enter more areas. He finds it "very credible" that doctors will intrude on pharmacy's turf and sell drugs.

Willis Goldbeck, President of the Washington Business Group on Health, outlined the role of the much talked about corporate health coalitions in his talk on "Employers as Megabuyers of Health Care." His theme was, "Don't look for anything terribly different from corporations than how we all do things." Corporate America controls the health care of 50 million employees, retirees, and dependents. "Most very big companies could buy out the best health care in their communities and foreclose the option of anything other than mediocre care for non-employees," said Goldbeck. Fortunately, corporations appear to be less selfish so far. Indeed, they are investigating such humanistic benefits as increased mental health care and payment for alcoholism treatment.

But cutting the corporate bill for health care will be difficult. Goldbeck said, "We don't know how to protect the excellence in the system from the impact of cost cuts while getting rid of the waste." Corporations will be working on that question over the next 30 years.

The net result of corporate intervention will be removal of traditional intermediaries in health care delivery, including insurance companies, doctors, and pharmacists. One current example: Rockwell International's on-site drug dispensing program.

To be Continued in the November Maryland Pharmacist



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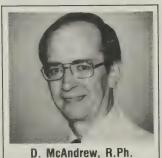
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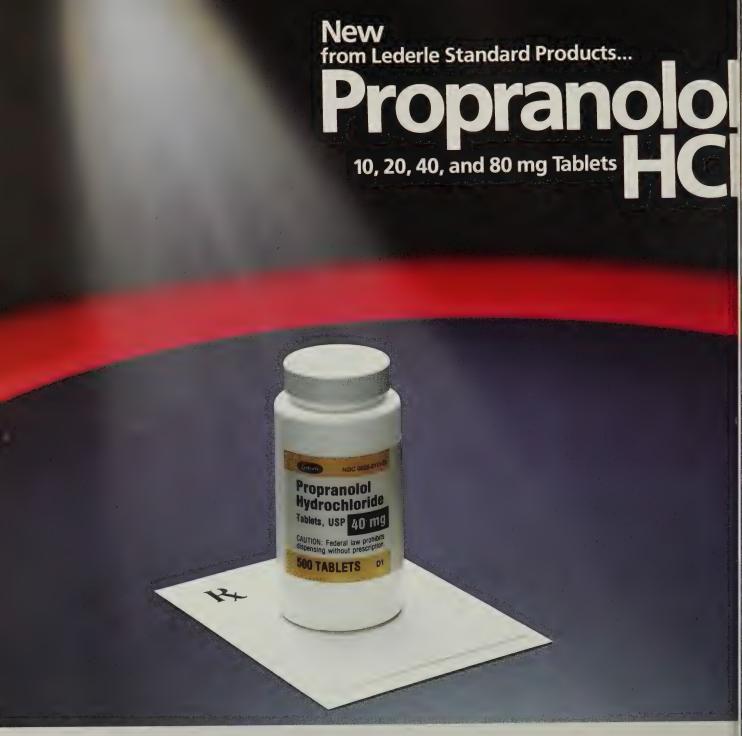
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Propranolol HCl is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARN-INGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol HCl.

WARNINGS:

CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol HCl should be discontinued (gradually, if possible)

IN PALIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of propranolol HCI therapy. Therefore, when discontinuance of propranolol HCI therapy. Therefore, when discontinuance of propranolol HCI is planned, the dosage should be gradually reduced over at least a few weeks and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If propranolol HCI therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol HCI therapy and take other measures appropriate for management of unstable angina pectoris. Since coronary artery disease may becamecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

NONALLERGIC BRONCHOSPASM (e.g., chronic bronchitis, emphysema).—PATIENTS W BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Propranolol HCI should be administered with caution since it may block bronchodilation duced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy to major surgery is controversial. It should be noted, however, that the impaired ability of theart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia surgical procedures

Propranolol HCI, like other beta blockers, is a competitive inhibitor of beta-receptor agorand its effects can be reversed by administration of such agents, e.g., dobutamine or iso proterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearan of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more diff to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid.storm. Propranolol does not distort thyroid fun

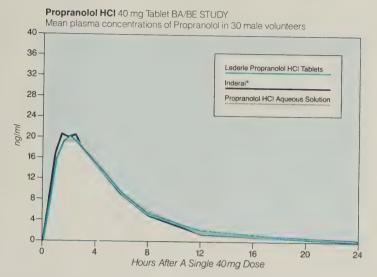
IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycard requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol

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Central Nervous System: Lightheadedness; mental depression manifested by insomnia, las-situde, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported

Miscellaneous: Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should ld that propranolol HCl may interfere with the glaucoma screening test. Withdrawal may to a return of increased intraocular pressure

cal Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, ted serum transaminase, alkaline phosphatase, lactate dehydrogenase.

G INTERACTIONS: Patients receiving catecholamine-depleting drugs, such as resershould be closely observed if propranoiol HCI is administered. The added catechole-blocking action may produce an excessive reduction of resting sympathetic nervous the which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or static hypotension.

nogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of signifigrug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosevels. Reproductive studies in animals did not show any impairment of fertility that was utable to the drug.

nancy: Pregnancy Category C. Propranolol HCl has been shown to be embryotoxic in al studies at doses about 10 times greater than the maximum recommended human

are no adequate and well-controlled studies in pregnant women. Propranolol HCl d be used during pregnancy and well-controlled studies in pregnant women. Propran Cl should be used during pregnancy only if the potential benefit justifies the potential

ng Mothers: Propranolol HCl is excreted in human milk. Caution should be exercised propranolol HCl is administered to a nursing woman

tric Use: Safety and effectiveness in children have not been established.

This and That About Pharmacy

by Leon Weiner, P.D.

Spotlight on Bernard B. Lachman University of Maryland Rx 1945

Two years ago, in May 1983, Bernard (Bunky) Lachman presented the 1983 Honored Alumnus Award to Charles H. Tregoe, Chief, Division of Drug Control. On May 23, 1985, it was time to change seats as Dr. Tregoe presented the 1985 Honored Alumnus Award to Dr. Lachman.

Following is the presentation made by Charles H. Tregoe at the great moment in the life of Bernard B. Lachman.

BERNARD B. LACHMAN, P.D. 1985 University of Maryland, School of Pharmacy Honored Alumnus Recipient

Dr. Bernard B. Lachman, or Bunky as he is affectionately known to almost everyone, is a native Marylander, a graduate of Forest Park High School and the University of Maryland, School of Pharmacy in 1945.

For the benefit of those who may not have the pleasure of knowing Bunky, he has always been, and continues to be, an individual who is caring, sharing, and giving of himself. Having been blessed with leadership ability and being a sharing person, he has shared this talent with not only his family and friends, but his chosen profession—pharmacy.

Soon after graduating from the School of Pharmacy, Dr. Lachman thought it important to not only be the master of his fate but to help mold the decisions that would govern his professional life. With this in mind, Bunky became an active member of the Baltimore Metropolitan Pharmaceutical Association and the Maryland Pharmaceutical Association. He served in practically every area of association work, and for the most part, he chaired the numerous committees he served. In 1969, he was elected President of the Baltimore Metropolitan Pharmaceutical Association, having previously been the Vice-President. Then in 1972, Bunky served as President of the Maryland Pharmaceutical Association. His total commitment, and deep involvement resulted in accomplishments which are too numerous to mention tonight. In addition to his association work, Dr. Lachman was appointed to serve as a member of the Commission on Crime and Dangerous Drugs by former Governor Theodore Agnew. He also served as Chairman of a curriculum revision committee for the University of Maryland, School of Pharmacy. Again, being a sharing person, and not wanting to slight the private sector, Bunky has been Vice-President and continues to serve on the Executive Committee of the A.I.D. drug stores. A major decision had to be made by Dr. Lachman after his tenure as President of the Maryland Pharmaceutical Association. He had just served on several important committees of the American Pharmaceutical Association and his services were becoming more in demand by the National Association of Boards of Pharmacy. It was at this time in 1975 that he had to decide whether to continue to serve the National Association of Boards of Pharmacy and proceed up the ladder or to devote his energies on a local level and serve the Maryland Board of Pharmacy. Fortunately, for the residents of Maryland, he elected to forego the National Association bid for his services and today, we see the results of his determinations.

Dr. Lachman was appointed to the Maryland Board of Pharmacy on May 1, 1976. Possessing the leadership qualities that he does and being the individual that he is, he was elected President of the Board in 1977 and has continued to serve in that capacity ever since. This honor continues to reflect his talent as being a leader among leaders. Having personally served as a commissioner on the Board of Pharmacy, I can truly convey that it was an honor to serve the Board during his presidency.

Under Dr. Lachman's leadership, a number of statutes or laws have been enacted while others have been repealed. Also, a number of regulations have been developed and promulgated while others have been amended. To mention just a few: Formal Hearings, Examination for Licensure and Internship Program; Transfer of Prescriptions Between Pharmacies; Security of a Pharmacy; Pharmacy Equipment; Standards of Pharmacy Practice; Monetary Penalties; Removal of Expired Licenses for Pharmacists; Closure of Pharmacies; Experience Required for Licensure by Reciprocity; and Reciprocity Fees. In mentioning fees, I might add that the Board's annual budget has increased from \$15,000 to \$150,000. Additionally, because of the increased activities of the Board under Dr. Lachman's untiring leadership, the Board's secretarial staff has increased threefold and has also employed an Executive Director. The Board's first newsletter in cooperation with the National Association of Boards of Pharmacy was developed and disseminated for the purpose of increasing lines of communication with the pharmacist.

Dr. Lachman was instrumental in the Board's supporting the development of the Pharmacist Rehabilitation Committee of the Maryland Pharmaceutical Association. From his vast experience in conducting formal hearings, and meeting with those pharmacists who had been charged with violating pharmacy laws, he saw the need for this program and has encouraged its growth.



Your appetite has only been whetted thus far, having briefly reviewed Dr. Lachman's professional career. The best has been saved for last. For now, I would like to speak of Bunky, the Family man.

Dr. Lachman was so very fortunate, for so many reasons, in having met Selma Berdiansky. Selma has contributed impeccably to Bunky's receiving the Honored Alumnus Award this evening. She too has been a sharing person in many ways. Bunky and Selma were married and here again Bunky also shared himself with Selma. They were blessed with three caring children, Diane, Larry, and Jan Ellen. Diane and her husband have blessed Bunky and Selma with two lovely grandsons. Fortunately, Larry and Jan Ellen have not blessed them with grandchildren. I say this since neither is married. However, Jan Ellen, a writer, is engaged to be married in September to her fiancee, Murray, who is an aspiring attorney. Larry resides in Los Angeles and exults his professional career as a writer and producer of television videos. Bunky has two brothers, Marc and Jack. Marc, who is also a pharmacist, and Bunky have been the proud owners of three pharmacies during their professional careers. They first owned a pharmacy on Bonaparte Avenue, then a pharmacy on Park Heights Avenue just one block south of Belvedere Avenue, and at this time, own Lachman's A.I.D. Store on Reisterstown Road in Reisterstown, Maryland. Jack, the youngest of the three, is an educator as well as a self-educated pharmacist assistant.

I could be loquacious about Dr. Lachman's professional accomplishments and loving family. Rather than continue to expound upon this gentleman's being, my preference is to introduce you to my friend and respected colleague.

Ladies and Gentlemen, it is my privilege and honor to now request that Dr. Bernard B. Lachman come forward and accept the University of Maryland, School of Pharmacy, 1985 Honored Alumnus Award. Dr. Lachman.

LOVE, MARRIAGE AND BABY CARRIAGE

Brenda Moore, UofMD Pharmacy 1984, will marry Dr. David Pelka on November 9, 1985 in Baltimore. Dr.

Pelka is a graduate of the Faculty of Dentistry at the University of Toronto and has a family dental practice in Windsor, Ontario where they will reside. The lucky couple met in Europe last summer during a tour of the continent.

Mark E. Prescop, UofMD Pharmacy 1982, has recently become engaged to Lynn S. Trout.

Linda Craig Klein, UofMD Pharmacy 1972, and her husband Bob, have been blessed with the birth of their second daughter, Jacquelyn, on March 14, 1985. Their first daughter, Dana, is 4½ years old. Linda works for the Medical Arts Pharmacy in downtown Baltimore.

When a man sees his children succeed in life, then he knows he has done a good job. Marion R. Chodnicki, UofMD Pharmacy 1951, is very proud of his three children and that feeling is reciprocated. Born and raised in East Baltimore, Marion went to Baltimore City College where he played varsity soccer. Immediately after graduation which was in 1943, he enlisted in the U.S. Navy where he served as a Pharmacist Mate for the Marine Corps in the Pacific area until 1947. Marion became so interested in pharmacy that he decided to enter the University of Maryland School of Pharmacy in 1948. While there, he did so well that he was elected to Rho Chi. After graduation from pharmacy school, Dr. Chodnicki worked for Rossberg Pharmacy and Leyko Pharmacy until 1954 when be bought Milton Pharmacy in East Baltimore. He stayed there for 16 years and ran a very successful pharmacy. During this time, he was very active in and became president of the Baltimore Metropolitan Pharmaceutical Association in 1965. In 1970, Marion decided to close Milton Pharmacy and went to work for several other pharmacies. At the present time, he is working for Drugfair at Route 29, Ellicott City, MD.

The children that Marion and his wife, Mary, are so proud of are:

- 1. Dennis Joseph Chodnicki, M.D.
 - specializes in Cardiology on the Eastern Shore
- 2. Marian Denise Chodnicki, P.D.
 - -1984 UofMD Pharmacy graduate
- 3. David Marion Chodnicki
 - -Electrical Engineer with IBM

This success story comes from an ambitious youth who was not born with a silver spoon in his mouth.

Pharmacy related from 1985 Pharmacy Class

- 1. Frank D. Mackowiak, son of Frank J. Mackowiak, UofMD Pharmacy 1962. Father works at Levay Pharmacy in Baltimore.
- Mark P. McDougall, son of Bernard McDougall, UofMD Pharmacy 1950. Father works at Mc-Dougall's Drug Center in Sykesville, MD.
- 3. Kathryn L. Parker, daughter of Hugh C. Hatch, Ferris State College Pharmacy School, 1958. Father works at pharmacy in Elk Rapids, MI.



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PHARMACY PEOPLE IN THE NEWS

Mitzi Schwartz graduated from the UofMD Pharmacy School in 1948. Because of her age, she could not take the pharmacy boards. Therefore, she went to work at a hospital pharmacy where she decorated pharmacy windows, signs and posters. She discovered that she was a true artist in many ways. Mitzi started doing replicas of wooden houses on plaques and has now developed a business of creating silhouettes for clients living in the Baltimore, Maryland; Washington, DC and New York areas. Sixteen years ago, she and her husband worked with the architects in the construction of their home. This proved that art was involved in her life. Mitzi married a pharmacist classmate, Jerry Schwartz, who then went on to become a dentist.

Jay Dorsch has been swimming since he was five years old. He was on the swim team when he was a student at Mount St. Joseph High School and also during the two years he attended Western College before transferring to the University of Maryland Pharmacy School. Two years ago, he began swimming competitively with the Maryland Masters team. Then not long ago, a friend told him about the second annual Race Across the Bay. Jay decided to enter and on a Sunday morning in June, the race began. About 66 people took part in the race. Dr. Dorsch swam from Sandy Point, around and under the bridge to Hemingway's Restaurant south of the far end of the span-a total of 4.1 miles. He did an excellent job finishing eighth in the race and for his age group, 30-39, he was second. Jay, who is a pharmacist at Voshell's Pharmacy in Baltimore, is the son of pharmacist Joseph U. Dorsch and the brother of pharmacists Barbara Dorsch Wirth and Margaret V. Dorsch. He is a 1978 graduate of the UofMD Pharmacy School.

The Catonsville Times is a weekly neighborhood paper which on June 19, 1985 carried an interesting article called "The Corner Drugstore" by Karen Schreier. It dealt with the problems of the individual owned pharmacies which are being threatened by discount prices from national drug store chains. Pictures featured pharmacists Ron Richardson of Medical Center Pharmacy, Catonsville and Melvin Rubin of Paradise Pharmacy. Comments from Dr. Ralph Shangraw, a Pharmaceutics Professor at the University of Maryland Pharmacy School, pharmacists Jay Dorsch, Herb Burns and Harry Willie were throughout the entire article. Most of the information is well known by most pharmacists, but it should really open a lot of non-pharmacists eyes.

When my classmate Herb Gerald Oster graduated from Pharmacy School in 1958, he was so young that he had to wait before taking the Pharmacy Board. Perhaps, while waiting, he decided to go the Medical School and become a physician. Now, Dr. Oster has established Maryland's first computer bulletin board system through which local medical people can exchange information. In fact Med Sig (meaning medical special interest group) may be the first computer bul-

letin board anywhere to which medical people are given free access.

PHARMACY CHANGES—June 1985

The following are new pharmacies:

Medicine Shoppe Family Pharmacy 6618 Belair Road 12962 Travilah Road Baltimore, MD 21206 Potomac, MD 20854

The following pharmacies closed up:

Vilma Pharmacy Kitchin Drug 3405 Belair Road 60 West Street Baltimore, MD 21213 Annapolis, MD 21401

Big B Pharmacy 790 W. North Avenue Baltimore, MD 21217

The following pharmacies have new names:

American Abbey
Homecare
7674 Standish Place
Rockville, MD 20855
(formerly American
Continue Care)
Joy Drugs
6305 Allentown Road
Camp Springs, MD 20748
(formerly Rodman's
Drugs)

PHARMACY RELATED DEATHS

Mrs. Hannah Tannebaum died June 15, 1985. She was

- 1. Mother of Stanley B. Tannebaum, UofMD Pharmacy 1966; wife—Linda
- 2. Mother-in-law of Stacy Pass, UofMD Pharmacy 1958; wife—Arlyn (Cookie)
- 3. Mother-in-law of Bernard Weisman, UofMD Pharmacy 1970; wife—Marilyn

Deepest regrets to Bernard Macek, UofMD Pharmacy 1956 and wife Treasure, on passing of daughter, Susan Christine, on June 21, 1985.

Deepest regrets to Ronald H. Kronsberg, UofMD Pharmacy 1960 and wife Elaine, on the passing of daughter Zena Nadine, on June 28, 1985.

William Cooley, 71, died in mid June 1985 in Cumberland. Bill, who graduated from pharmacy school in 1932 was the original owner of Potomac Valley Pharmacy and later worked at Memorial Hospital in Cumberland.

Leonard H. Kramer, UofMD Pharmacy 1932, died on June 9, 1985. Dr. Kramer, 74, used to work for Clayman's Pharmacy in Baltimore.

Jennie Leberman, 84, died July 4, 1985. A graduate of UofMD Pharmacy 1922, she had worked for Wager's Drug Store and for the family owned Brookfield Pharmacy.

Charles R. Kesmodel, Sr., UofMD Pharmacy 1932, died July 13, 1985. Dr. Kesmodel, 74, worked many years for the Read Drug and Chemical Company in Baltimore.

Managing in the 90's and Beyond

by Dean Leavitt, Ph.D.

In the complete involvement of a community or hospital practice and the need to update one's drug knowledge, it is quite possible for the pharmacy owner/manager to miss out on changes taking place in management.

Two very important books were published in the early 1980's which are impacting managers at all levels of American business. Each emphasizes the manager's relationship with people. One, the people we work with; the other, the people we serve.

The best seller of the two is Peters and Waterman's, "In Search of Excellence" (1). The authors have sublimated the essence of America's most successful firms into eight basic principles. Granted the authors researched the larger firms and some of the ideas might not be applicable to the small firm, a number are applicable to firms of any size.

Principle One: A bias for action: a preference for doing something—anything.

With larger firms it is usually a question of overstudy, oversearch until one gets so sick of the proposed solution, it is applied only half heartedly. With small businesses, it is probably more procrastination than overstudy, putting it off hoping it will go away.

An action manager perceives the problems and utilizing the people and other resources available, puts into action a flexible solution and controls its application as the problem is solved. Solve the problem before you and your co-workers lose your enthusiasm!

Principle Two: Staying close to the customer/patient learning her preferences and catering to them.

The authors recommend a much more active role for managers than may be the current practices in pharmacy. Periodic discussions with customers and staff on practice services, detailed follow up of complaints, a return to the idea that if the patient is not completely satisfied with our service, she may not return.

Principle Three: Autonomy and entrepreneurship—breaking the firm into smaller divisions and encouraging them to think independently and competitively.

Perhaps less applicable to the small business environment of pharmacy practice but with larger community and hospital pharmacies, it involves more authority to department/division managers and a challenge to make them more efficient and profitable. Coupled with principle four, giving each employee the incentive to succeed as an individual *and* a member of the firm.

Principle Four: Productivity through people—creating in all employees the awareness that their best

efforts are essential and that they will share in the rewards of the firm's success. Each employee is an important link in the health care system selected by your patients, and thought and care is essential to the proper servicing of each patient. The more successful the practice is in providing patient services, the more profitable the firm should be and all members of the group should share in the profits generated.

Principle Five: Hands-on, value driven—insisting that owners managers keep in touch with the firm's essential business. What do you want your practice to be? Where do you want the firm to be in ten years? What do you believe are the basic essentials of practice? These contemplations evolve into a simple set of inviolate beliefs necessary to maintain the practice you have defined.

Members of the firm are given all sorts of autonomy and incentive to be themselves in the success of the firm, but not to violate one of these basic beliefs. The successful firm has a well defined set of guiding beliefs, well known to owners, managers, employees and customers.

Principle Six: Stick to the knitting—remaining with the business the firm knows best. Do not spend a lot of resources on areas in which you have little or no expertise. Stick to pharmacy, health care and patient service. If you have the spare time and resources, become an expert before you jump onto a currently attractive fad. Durable medical equipment can be very attractive but takes a degree of expertise that is not always common to pharmacy. It takes resources and training that may reduce the firm's effectiveness in providing its basic pharmaceutical service.

Principle Seven: Simple form, lean staff—few managers. Probably not a problem with small firms which do not have the communication problems of the large firm. Theory Z will also mention the need for lean management structures.

Principle Eight: Simultaneous lose tight properties—fostering a climate where there is dedication to the central beliefs of the firm combined with tolerance for all employees who accept those values (and a total lack of tolerance for all who do not). The authors indicate that this is sort of a summary principle and stress again the importance of complete dedication to the basic beliefs developed for a firm. They also emphasize the importance of smallness, the smaller the firm, unit, division, the more efficiently it may be operated. The smaller the firm, the easier it is to motivate and com-

municate with the employee.

"In Search of Excellence" is an excellent addition to the management literature and worthwhile reading to all who wish to improve their management skills.

The second book is William Ouchi's "Theory Z How American Business Can Meet the Japanese Challenge (2).

Basically, Theory Z establishes a work culture that has a distinct set of values. There are not boss-worker, employer-employee relationships, rather the atmosphere is one of a group of fellow human being trying together to achieve organizational goals.

Of all of its values, commitment of a Z culture to its people—its workers—is the most important. Theory Z suggests that humanized working conditions not only increase productivity and profits to the organization but also the self-esteem of the employee.

Basic Assumptions of Theory Z:

- 1. All members of the company are valued and trusted and are equally important to the achievement of organizational goals.
- 2. A long time commitment by the employee and company is much more conducive to productivity and responsible, equitable behavior towards one another.
- 3. All members of the organization have been rotated through most of the jobs in the organization and are thereby empathetic to the problems faced by the various members.
- 4. Because of the long term commitment to each employee, there is much less pressure for rapid promotion with the firm.
- 5. As with most management philosophies theory Z must be adopted and used by upper management as an example to all other members of the organization.
- 6. The concept of assumed responsibility is accepted. The one who discovers the need, assumes the responsibility to get it done.

Both books have profound implications for managers and workers in the future. Hopefully, it will remove the sharp distinction between the two groups, and coalesce them into a much more congenial, productive group.

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- Ouchi, WG. "Theory Z How American Business Can Meet the Japanese Challenge", Addison-Wesley Publishing Co., Reading, Mass. 1981.

A Preview of Independent Community Pharmacy—1985

The current year's preliminary *Lilly Digest* report, compiled from 1984 operating data submitted by 1,078 independent community pharmacies, indicates that the cost-of-goods-sold percentage remained unchanged, whereas total expenses declined slightly and resulted in a higher net profit before taxes. When the profit and loss statement items are compared with similar figures for 1983, they show that . . .

Total sales attained a record high of almost \$564,000, up more than 6% over the 1983 figure. This rate of increase is lower than the average annual growth rate of 9.9% observed over the past decade. Prescription sales gained almost 11% when compared with the previous year's figure and substantially outpaced other sales, which rose only 0.7%. Prescription income accounts for almost 61 cents of every revenue dollar.

Gross margin advanced more than 6% in dollars but remained unchanged as a percent of total sales. Total expenses fell percentagewise to a record low of 30.1% (down from 30.2% during 1983). This reduction was the result of declines in both manager's salary and employees' wages, which more than offset the increase in miscellaneous operating costs. The combined effect of these changes was that net profit before taxes rose to 3.0% of sales.

Although total expenses declined percentagewise, they did rise in terms of dollars (up almost \$10,000, or 6.3% from the previous year). The average proprietor's or manager's salary also was higher in dollars but decreased to 5.9% of total sales. Employees' wages advanced dollarwise but declined as a percent of sales (down from 10.8% to 10.5%, the lowest level since 1953). Rent moved up about 6% in dollars but remained unchanged at 2.4% of sales. Miscellaneous operating costs gained almost \$6,000, a 10% increase over the year earlier. In addition, these costs took a larger share of the sales dollar—up from 11.0% to 11.3% of total income.

Net profit before taxes grew more than 7%, with a \$1,160 increase over the 1983 figure. Total income (proprietor's salary plus net profit before taxes) advanced to almost \$50,000, a 5.2% increase, but declined slightly as a percent of sales volume to 8.8%.

Although both prescription and over-the-counter inventory requried a greater dollar investment, prescription stock decreased from 10.7% to 10.6% of prescription income, whereas general merchandise inventory remained the same at 20.9%. The prescription department's sales productivity increased to \$9.42 per stock dollar—up from \$9.34 recorded

for 1983. Other merchandise sales productivity was unchanged at \$4.79.

Renewed prescriptions rose as a percent of total prescriptions to 51.3% and continued the uptrend that began five years ago. At that time, renewed prescriptions had declined steadily for over a decade. The share of renewed prescriptions is considered important, since it reflects the degree of patient loyalty enjoyed by a pharmacy. The average prescription charge advanced to about \$12.00 (\$11.99) during 1984, an increase of \$1.10 (10.1%) over the 1983 figure of \$10.89.

The size of the average *Lilly Digest* pharmacy remained essentially unchanged during 1984 at just under 2,500 square feet. Sales productivity per square foot of selling space increased approximately \$18 (up to \$229.64) from the previous year—an 8.6% increase. The typical *Lilly Digest* pharmacy was open one hour less during 1984 at 61 hours per week.

The following table summarizes the operating figures of 1,078 independent community pharmacies and compares these with the 1984 *Lilly Digest* average of 1,547 stores. The 1985 edition of the *Lilly Digest* will be distributed during September of this year.



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Lilly Digest Preliminary Report - 1985

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Averages per Pharmacy	1984 Preliminary Sample (1,078 Pharmacies)	1983 Full Sample (1,547 Pharmacies)	Amount and Percent of Change
Sales Prescription Other Total	\$ 342,717— 60.8% 221,075— 39.2% \$ 563,792—100.0%	\$ 309,354— 58.5% 219,510— 41.5% \$ 528,864—100.0%	+\$ 33,363—10.8% +\$ 1,565— 0.7% +\$ 34,928— 6.6%
Cost of goods sold	377,465— 66.9%	<u>353,673</u> — 66.9%	+\$ 23,792— 6.7%
Gross margin	\$ 186,327— 33.1%	\$ 175,191 — 33.1%	+\$ 11,136— 6.4%
Expenses Proprietor's or manager's salary Employees' wages Rent Miscellaneous operating costs Total expenses	\$ 33,057— 5.9% 59,454— 10.5% 13,225— 2.4% 63,931— 11.3% \$ 169,667 30.1%	\$ 31,775— 6.0% 57,323— 10.8% 12,489— 2.4% 58,104— 11.0% \$ 159,691— 30.2%	+\$ 1,282— 4.0% +\$ 2,131— 3.7% +\$ 736— 5.9% +\$ 5,827—10.0% +\$ 9,976— 6.3%
Net profit (before taxes)	\$ 16,660— 3.0%	\$ 15,500— 2.9%	+\$ 1,160— 7.5%
Total income	\$ 49,717— 8.8%	\$ 47,275— 8.9%	+\$ 2,442— 5.2%
Value of inventory at cost and as a percent of sales Prescription Other Total	\$ 36,385— 10.6% 46,132— 20.9% \$ 82,517— 14.6%	\$ 33,132— 10.7% 45,814— 20.9% \$ 78,946— 14.9%	+\$ 3,253— 9.8% +\$ 318— 0.7% +\$ 3,571— 4.5%
Annual rate of turnover of inventory	4.6 times	4.6 times	
Number prescriptions dispensed New Renewed Total	13,928— 48.7% 14,665— 51.3% 28,593—100.0%	13,887— 48.9% 14,517— 51.1% 28,404—100.0%	+ 41— 0.3% + 148— 1.0% + 189— 0.7%
Average prescription charge	\$ 11.99	\$ 10.89	+\$ 1.10—10.1%
Size of floor area*	2,470 sq. ft.	2,479 sq. ft.	
Sales per square foot*	\$229.64	\$211.56	+\$ 18.08— 8.6%
Pharmacy hours open	61	62	

^{*} Based on averages of pharmacies that reported all data.

Guidelines for Pharmacy Computers

Nick Lykos & Allen Novak

The practice of Modern Pharmacy demands a system of recording and storage of prescription and drug information that to only precise, but easily accessible. Considering volume of information needed to be stored and retunded, today's pharmacist must have an easily manageable system of record keeping if he is to be competitive. There is little wonder why automated data processing systems have been so popular in pharmacy.

But the majority of pharmacies today do not utilize a computerized record keeping system. And those that have systems already may not be able to store and retrieve all of the information that they really need. It is the purpose of this article to provide some guidelines for the recording and storage of prescription information using an automated data processing system.

- A. All information relative to a prescription should be entered into the system including, but not limited to, the following:
 - 1. The prescription number.
 - 2. The patient's name and address.
 - 3. The prescriber's name.
 - 4. The prescriber's DEA number, if appropriate. The system should comply with all DEA regulations regarding Schedules II, III, IV and V.
 - 5. The name, strength, dosage form, and quantity of the drug prescribed and dispensed originally and upon each refill.
 - 6. The number of refills authorized.
 - 7. The date of issuance of the prescription.
 - 8. The date and identifying designation of the dispensing pharmacist for the original filling and each refill.
 - 9. The system should be able to note special instructions such as "DAW", trial-size quantities and handle partial refill quantities.
- B. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The record of such entries should be preserved by the pharmacy for a period of five (5) years from the

- time of the prescription's last activity. (A total of five years "on-line" and printed copy of purged records).
- C. The system should provide adequate safeguards against improper alteration of the records.
- D. The system should be capable of producing a printout of all original and refill prescription data. This includes, but is not limited to, a prescription-by-prescription and refill-by-refill audit trail for any specified strength and dosage form of a controlled substance, brand or generic, or an audit trail of controlled substance prescriptions written for a particular patient.
- E. The system should be capable of printing a log (printed daily, weekly or monthly). This log should be maintained for a period of five (5) years.
- F. An auxiliary record keeping system shall be established for the documentation of new and refill prescriptions if the automated data processing system is inoperative for any reason. When the automated system is restored, all information should be entered into the system within a reasonable period of time (72 hours).
- G. A pharmacy should make arrangements with the supplier(s) of data processing services to assure that the pharmacy continues to have complete prescription dispensing records (hardware & software maintenance contracts).
- H. Computerized systems should statisfy all requirements regarding the transfer of prescriptions between pharmacies.
- I. Purged prescription information must be retrievable in hard copy and should include:
 - 1. Patient's name & address.
 - 2. Prescription number.
 - 3. Dates of original and all refills with pharmacist's initials.
 - 4. Drug description.
 - 5. Refill status at time of purge.
 - 6. Directions for use.
 - 7. Prescribing physician.
- J. All automated data processing systems must provide a file back-up system, and the back-up media must be properly maintained and stored.

Nick Lykos is Pharmacist/Owner of Lykos Pharmacy, York & Timonium Rds., Timonium, MD 21093 (301) 252-4225.

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Cathy A. Davis has been assigned to the Baltimore territory for the Upjohn Company. Cathy is a graduate of the University of Vermont.



Pictured from left to right: Frank X. Radigan, District Manager, Merck Sharp & Dohme and John M. Kozitzky, Region Director, Mid-Atlantic, Merck Sharp & Dohme present a check for \$20,000 as the second installment of a three year Merck Foundation research grant to Dr. Peter P. Lamy, Professor and Chairman, Pharmacy Practice and Administrative Science Dept., Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly and Dr. Donald O. Fedder, Associate Professor, Pharmacy Practice and Administrative Science Dept., Director, Pharmacy Practice Programs of the University of Maryland School of Pharmacy.



Zoe Vette has been assigned to the south Maryland area as a representative of the Syntex Company. She is a graduate of the University of Maryland.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

THALIDOMIDE:

Severe recurrent oral ulcerations cause painful conditions and intense dysphagia. If genital involvement is present, symptoms of dysuria and dysparenia are also seen. Many therapies have been tried and found to be either ineffective or too toxic to recommend for general use. In a trial using thalidomide in a double blinded manner, investigators were able to produce complete resolution of the problem in 14 of 15 affected patients. The other patient improved significantly. Adequate contraceptive methods were taken in women exposed to the drug. Trials using glutethimide (Doriden) in a similar manner were ineffective even though glutethimide is closely related chemically to thalidomide. *Lancet*, Vol. II, #8417, p. 1424, 1985.

DEFEROXAMINE:

Patients with excessive aluminum concentration in their bones show vitamin D resistant renal osteodystrophy characterized by muscle and bone pain. Deferoxamine infusions have increased the mobility of the aluminum from bone and tissue and thus must serve as a diagnostic method for determining the status of aluminum in the body. Deferoxamine is a biologically-acquired product used in the removal of excess iron from the body. *Ann Intern Med*, Vol. 101, #6, p. 775, 1984.

VITAMIN A:

A mild deficiency of vitamin A is thought to exist extensively in children in developing nations. Various ophthalomological signs and symptoms have been recognized as more attention is given these children. A deficiency in the dietary intake of vitamin A is thought to be responsible for production of the symptoms. *JAMA*, Vol. 252, #22, p. 3086, 1984.

PROGESTERONE:

Men and women newly diagnosed as hypertensive and not on any antihypertensive medication were treated with oral doses of natural progesterone or a placebo preparation. Progesterone has generally been classified as being hypertensive, but in this group of eight men and four post-menopausal women the hormone was found to reduce blood pressure significantly. Progesterone may play a role in the regulation of normal blood pressure and further experiments need to be performed to see if it does indeed have a role to play in the treatment of hypertension. *Br Med J*, Vol. 290, #6461, p. 13, 1985.

BETA ADRENERGIC BLOCKING AGENTS:

Metoprolol (Lopressor), propranolol (Inderal), or nadolol (Corgard) were administered orally three times daily for four days and volunteers were evaluated to

determine the degree of inhibition in exercise-induced tachycardia, alterations which might occur in hepatic blood flow, and hepatic enzymatic activity. Plasma levels of the antagonists were determined to insure presence of the drug. Metoprolol produced the greatest inhibition in exercise-induced tachycardia. While all three drugs reduced hepatic blood flow to some degree, the effect was most significant with propranolol. Enzymatic activity of the liver, as measured by antipyrine clearance rates, was inhibited by 36% when the patients received propranolol, but only a 12% reduction was seen when other beta blocking agents were being administered. *J Clin Invest*, Vol. 24, #11, 12, p. 493, 1984.

CALCIUM AND SPERM FUNCTION:

Calcium ions have been found to have a variety of effects on the development and activation of human and animal sperm cells. In the epididymus, the area where sperm mature and become mobile, calcium ions are seen to act as a stimulation to the maturation process. Male organs such as the seminal vesicle and the prostate gland secrete fluids which mix with the sperm. These fluids have been found to contain substances which bind calcium ions and also prevent the transport of calcium through membranes. Physiologically these lower concentrations of calcium ions are necessary because it seems as if high calcium concentrations have an inhibitory activity on the mobility of mature sperm. Calmodulin has been suggested to be a critical factor in reversing the sensitivity of sperm cells to calcium concentrations. Lancet, Vol. II, #8417, 8418, p. 1449, 1984.

TRANSDERMAL CLONIDINE:

A group of seven patients were treated for hypertension with the alpha-2 stimulant clonidine (Catapres) administered as a transdermal disc to test efficacy and safety. The patches were designed to release clonidine at a constant rate over a seven-day period of time. Although the efficacy of the preparation was evident, side-effects such as local skin erythema and dry mouth were common. *JAMA*, Vol. 253, #2, p. 233, 1985.

AMINOPURINE:

Although acyclovir (Zovirax) has been shown to be the most effective substance yet marketed for the treatment of herpes simplex and herpes zoster viral infections, only about 20% of an orally administered dose is absorbed from the gastrointestinal tract. A precursor of acyclovir which is metabolized to the parent compound by the xanthine oxidase system has been synthesized by Burroughs Wellcome and Company. The drug is more completely absorbed and may represent an improvement in therapeutic response to an orally administered drug. *Lancet*, Vol. II, #8417, #8418, p. 1428, 1984.



MAIL ORDER PHARMACY

A Growing Public Health Hazard

ace-to-face communication between patient and pharmacist has been a vital component of pharmacy practice since its inception. Pharmacists interact daily with patients in their stores: they monitor their patients' health status, assess their compliance with drug therapy, answer questions, make recommendations, and communicate with their physicians. Patients know they can count on the pharmacist to provide expert advice on drug therapy on the spot and personally attend to their individualized health care needs. This face-to-face communication is a key element in ensuring that the public health will be protected.

Community pharmacists are concerned, however, because this essential patient-pharmacist contact does not exist in mail order drug delivery systems, and thus places the health of consumers in jeopardy. It is impossible for mail order firms to know if a patient lacks complete understanding of how and when medication should be taken. They cannot visually assess the patient and truly understand the interrelationship between the patient's health problems and the recommended drug therapy. They also have no knowledge of OTC drugs the patient may be taking or other pertinent information.

STRIKING DISTINCTION

The differences between the services of a community pharmacy and a mail order firm are striking. Studies have shown that community pharmacists spend a minute and a half consulting with customers on each prescription. Assuming an eight-hour day and an average of 75 prescriptions filled per day, a pharmacist devotes nearly two hours—or 23 percent of each day—to face-to-face counseling on patients' prescription needs. The same research also found that pharmacists answer about 25 questions a day concerning prescriptions. In an average week, they are asked 29 questions about the reasons for taking a particular drug, 28 questions about refills, 28 questions about side effects, 18 questions about food or drug interactions, and 13 questions about dosages.

Nearly 75 percent of pharmacists say patients today rely more on them for professional advice than they did three years ago. Some studies indicate that community pharmacists spend as much as 35 percent of their day consulting with patients. The need for this direct consultation is highlighted by another study that found that more than half of all patients have an inadequate understanding of the terms used in prescribing medications and clearly need the pharmacist's consultation. A third of the patients in another sample were unaware of what was expected of them regarding specific instructions for taking their medication. Fifty-eight percent of the drugs used by this group were taken more frequently or less frequently than prescribed or were taken at inappropriate times. But when patients were properly informed about what was expected of them, they took the medication as directed more than 85 percent of the time.

The elderly pose special drug compliance problems. Reports indicate that 12 to 17 percent of all elderly patients in the U.S. admitted to acute care hospitals are the victims of adverse drug reactions—due in large part to noncompliance by the patient.

SUSPECT QUALITY

Given these facts, it is no wonder that responsible community pharmacists are concerned about the public health hazards posed by mail order programs. These firms can potentially monitor only one aspect of the patient's health—maintenance drugs. They may have computers to access drug information, but they are still only examining the interaction of maintenance drugs, not the patient's entire drug therapy. The bottom line is that mail order firms cannot provide adequate health care to patients they never see. In addition, the integrity of a drug distribution system that relies exclusively on the mails is anything but certain, and the quality of drugs dispensed in volume, long distance, and often left to languish in mail boxes or inside screen doors is no less suspect.

The National Association of Retail Druggists, through its Mail Order Task Force and Clearinghouse, is studying the public health hazards of mail order drug programs and collecting data to guide legislative and regulatory reforms. If you want your patients to know why mail order drugs are no bargain, NARD has produced an informative brochure, available in quantity—\$6 for 50 copies, \$10 for 100 copies—by writing National Association of Retail Druggists, 205 Daingerfield Road, Alexandria, Virginia 22314.

FYI, a monthly perspective on topics of interest to pharmacists, is provided as a service by the National Association of Retail Druggists.

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The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Cromwell Bridge Road Beltway Exit No. 29. For further information contact President Frank Block (phone: 358-2743). This organization has several veteran pharmacists available for part-time employment.

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Oct. 21-24—NARD Convention, New York City Nov. 10 (Sun.)—CECC Seminar on Infectious Dis-

Nov. 14-MSHP Meeting, University of MD Hos-

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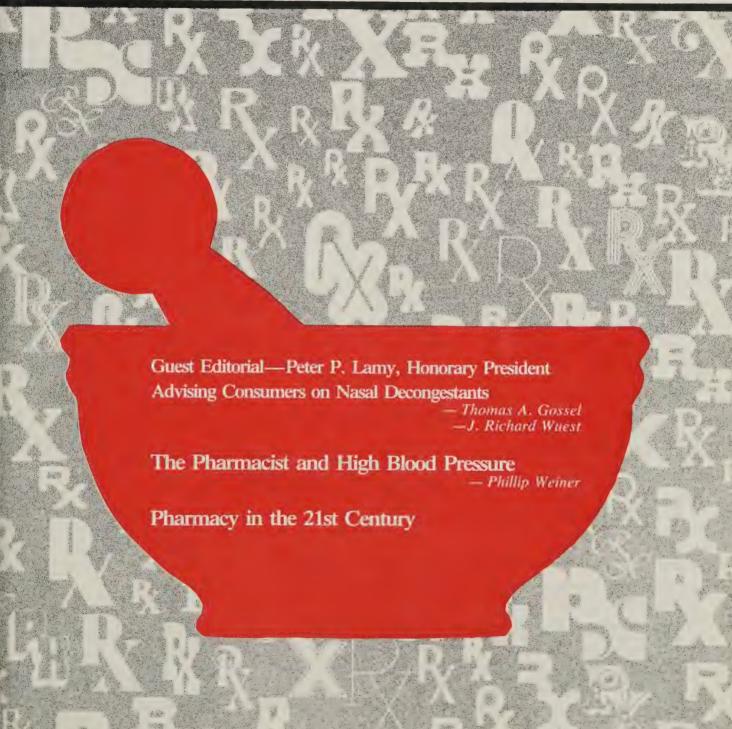
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THE MARYLAND PHARMACIST

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Guest Editorial

Practitioner and Ivory Tower—The "Bulletin Board"

by
Peter P. Lamy, Ph.D., Hon. President
Maryland Pharmaceutical Association

Community Pharmacy, as we know it, is threatened. HMOs present the secondfastest growing segment of organized health care. Hospitals, reeling under the impact of the DRGs, look to community services (home health care) to retain "their" patients. New York and some Veterans Administration facilities have undertaken to test the Resource Utilization Groups, first cousin (for the ambulatory area) of the DRGs. Others attempt to ship drugs into physicians' offices and advise that they could be dispensed for a fee. The chains are expanding and one can walk through cities such as Salt Lake or Denver without finding a traditional community pharmacy. The issue of generics is not yet settled (Sen. Orin Hatch seriously questions some of the FDA parameters used to declare generic substitutes as "equivalents." Yet he was the prime mover for the 1984 amendments) and therapeutic substitution is right around the corner. Pennsylvania fought the battle against vans rolling through the countryside, dispensing drugs, and in New Mexico, nurses and physicians, in sparsely settled areas, wanted to carry full "black" bags and dispense on the spot. Finally, there is mail order. Aside from the Veterans Ad-

ministration and the American Association of Retired Persons, there are nine players in the field. Together they dispense some 32 million prescriptions a year, and the players and the volume are growing. Predictions are that some chains will enter the field forcefully, soon. Large companies (Ford, GM, United Technologies, Pitney Bowes, Burroughs, National Arthritic Foundation, Uniroyal, Firestone, unions and HMOs) are the best customers.

Why not look to the School of Pharmacy for help? What are they doing? Is the Dean really promising a "Bulletin Board" for all those pharmacists that have a computer, so they can be tied directly to the School's computer efforts, which have been massive and promise to continue. A "Bulletin Board"? So the practitioner can hear about aspirin and Ipecac Syrup? Who needs it? And why put "my" data on the computer network?

Why, indeed?

Perhaps there are other, much greater benefits to be reaped—that can be of real help. Let's look at one. One reason that mail order prescriptions are finding more and more favor is the fact that they dispense a larger prescription—perhaps three months worth. Savings: dispensing fee. And under the

RUGs, there will be larger prescriptions. Savings: Visits to the clinic. These are "projected" savings, and an integrated computer network can help collect data which show how many of these large prescriptions are discontinued—with the unused portion of the prescription not being used, but remaining at home. How much money is lost? What are the dangers of diversion and drug abuse?

There is, to be sure, an even greater benefit. Many of the major pharmaceutical companies are looking for "data bases." Clearly, the time is approaching for post-marketing surveillance. Defined patient populations, using drugs, will be worth their weight in gold—literally. The mail order businesses have all kinds of data on their computers, data that will look appealing. Yet, the individual community pharmacist, having possibly more detailed data, can't compete. But can a consortium of community pharmacists—using that "Bulletin Board." Can community pharmacy provide yet again a very necessary service and gain some economic advantage? Surely it can—and here is an opportunity to bring the Ivory Tower into the daily arena. Let's grab the chance. It is here.



NOVEMBER, 1985

SCOPI

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 10

Advising Consumers On Nasal Decongestants

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and
Toxicology
Ohio Northern University
Ada, OH
and
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Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
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Goals

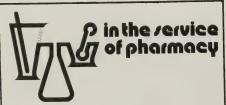
The goals of this lesson are to:

- discuss the actions and uses of OTC nasal decongestants;
- 2. explain how to advise patients on their use.

Objectives

At the completion of this lesson, the successful participant will be able to:

- identify the pharmacological action of the described OTC nasal decongestants;
- 2. choose the appropriate agent for a given situation;



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC. © Merrell Dow 3. explain the proper technique for instilling the products.

Nasal congestion, more commonly referred to as stuffed-up or stuffy nose, is usually caused by the common cold. However, allergic rhinitis, bacterial infection, local or viral inflammation, anatomical defects and emotional upset can also result in nasal congestion.

Congestion occurs in the nose when capillaries serving the nasal mucosa respond to irritants (both external and internal) by dilating. Fluid seeps from these enlarged blood vessels into the tissues of the sinus areas and nasal cavity causing localized edema with swollen nasal passages. This is all part of the natural inflammatory response. Histamine, due to its vasodilatory effects is the causative agent making breathing through these inflamed passages difficult. Since fluid exudation increases (a normal cholinergic activity) with the common cold, sinus and nasal discharge can accompany the congestion.

In this lesson, the actions and uses of nasal decongestants will be highlighted with an emphasis on products that are safe and effective for OTC use. Several of these were formerly available only on prescription. Consumer advice will be presented, along with suggestions to aid individuals in overcoming the decongestant "habit."

Function Of The Nose

The nose alerts us to pleasant, unpleasant and noxious odors. It is the beginning of our "natural humidifier." In order for the lungs to function properly, air delivered to them from our environment should be at or near 100% relative humidity. Relative humidity refers to the amount of moisture in the air as compared to the total amount of water that the air can contain at that temperature. For ex-

ample, when it is raining, the air is a 100% relative humidity. One rule o nature is that warm air holds mor moisture than cold air.

Usually, the air around us range from 40 to 75% relative humidity. The numerous blood vessels in the nose raise the relative humidity of inspired air by warming it so that it can hold more water. They also supply moisture. This air is then carried past the nasopharynx and larynges area where it picks up even more moisture. These same blood vessel when dilated, cause nasal congestion.

The nasal mucosa contains cell which secrete mucus that is normally transported by ciliary action as continuous layer backward into the nasopharynx, along the pharynge wall, and then into the esophage where it is swallowed. This fluit also lubricates the pharyngeal and laryngeal mucosal surfaces in the process. When excessive fluid is produced, it can drain out of the nostri (i.e., during the common cold or has fever) or drain into the trachea in tating the tissues (i.e., post nas drip).

Nasal Decongestants

Chemically, nasal decongestan are sympathomimetic amines. Pha macologically, they stimulate the apha adrenergic receptors of vascul smooth muscle which are excitator and constrict dilated arterioles. I lated vessels located within the r sal mucosa become smaller and le engorged with blood. This decrees the edema and consequent improves nasal ventilation and drainage. Headache resulting frecongested sinuses may also be allegated.

Decongestants can be taken ora or applied directly to the nasal national properties. Phenylpropanolamine are pseudoephedrine are effective orally. Neither shows significant activities when applied locally.

THE MARYLAND PHARMACIST

Effective topical decongestants are phedrine, levodesoxyephedrine, aphazoline, oxymetazoline, phenlephrine, propylhexedrine and xyometazoline. Trade names for those roducts are listed in Table 1.

TABLE 1 Representative OTC Nasal **Decongestants**

opical Ingredients	OTC Products		
phedrine	Efedron, Vatronol		
evodesoxyephedrine	Vicks Inhaler		
aphazoline	Privine		
xymetazoline	Afrin. Dristan Long Lasting, Duramist Plus, Duration, Neo-Synephrine 12 Hour, Nostrilla, Sinex Long Lasting		
nenylephrine	Alconefrine, Allerest, Coricidin, doktors Nose Drops, Duration Mild, Neo- Synephrine, Nostril, Rhinall, Sinarest, Sinex		
opylhexedrine	Benzedrex Inhaler		
/lometazoline	Chlorohist-LA, 4-Way Long Acting, Neo-Synephrine II Long Acting, Otrivin, Sinutab Long Lasting		
stemic Ingredients	OTC Products		
nenylpropanolamine*Decongestant-P, Propagest, Rhindecon			
eudoephedrine*	Afrinol, Cenafed, Kodet SE,		

Ephedrine, levodesoxyephedrine, phazoline, phenylephrine, and opylhexedrine are relatively shortting topical nasal decongestants. ie dosage regimen is usually every to 4 hours.

oth of these agents are included in numerous

ombination cough and cold remedies

Novafed, Sudafed

Ephedrine has bronchodilatory, NS stimulant, and vasopressor hen given by injection) activity. It one of the oldest drugs, and has en used in China for centuries. hedrine has been used as a nasal congestant in this country since mid-1920's, but its use has deased in recent years and now is alost obsolete.

phazoline is reportedly a more tent vasoconstrictor than the other ort-acting topical decongestants. A 5% solution of naphazoline is ually effective as a 0.5% solution lephedrine or phenylephrine.

'henylephrine has been widely ed in a variety of systemic cold nedies for many years. It is a safe d effective decongestant when

led orally.

evodesoxyephedrine and propyl**kedrine** are volatile amines that be incorporated onto a cotton k and used in an inhaler (e.g.,

Benzedrex, Vick's Inhaler). The characteristic smell is due to the volatile oils that are added, not the active ingredient. Since they are equally effective, the choice of which inhaler a person prefers is based on subjective opinion or personal preference.

Oxymetazoline and xylometazoline are longer acting than the aforementioned topical agents with some individuals obtaining 10 to 12 hours of decongestant activity from a single dose. They, most specifically oxymetazoline, have captured a major share of the OTC market place. Apparently their more convenient dosage regimen and lower incidence of rebound congestion (to be explained shortly) makes them agents of choice. These two agents were among the first of the OTC drug products shifted from prescription only to OTC status during the flurry of such activity in 1981 and 1982.

Phenylpropanolamine and pseudoephedrine are safe and effective oral agents for self-treatment of "stuffy" nose. After absorption and distribution to the vascular bed in the nasal mucosa, they provide a less intense but more sustained action than the short-acting topical agents.

Relatively speaking, phenylpropanolamine exerts a greater CNS stimulatory effect than pseudoephedrine. In fact, phenylpropanolamine has been determined to be safe and effective by the FDA advisory panel that reviewed OTC appetite appeasers. It is the principle active ingredient of most diet aid products.

Pseudoephedrine reportedly causes fewer CNS effects than does phenylpropanolamine, and is available in more single entity decongestant products. They are included in combination OTC cough and cold remedies in about the same proportion. Both are available in regular and sustained-action oral dosage forms.

Adverse Effects

Used as directed, nasal decongestants rarely cause adverse effects, especially the topically applied agents, because very little is absorbed into general circulation. There have been isolated reports that phenylpropanolamine, in very high doses, may cause severe headaches and hypertensive reactions. All of the decongestants, because they are sympathomimetic amines, have a potential for

causing various CNS effects. These adverse reactions are listed in Table

TABLE 2 Adverse Effects Reported For Systemic Nasal Decongestants*

Bradvcardia Cardiac arrhythmias CNS stimulation Coma Deep sleep Dizziness **Drowsiness** Headache Insomnia Nausea Nervousness **Palpitations** Rebound hypotension Sweating Trachycardia Transient hypertension

*Not all effects have been reported for all systemic nasal decongestants.

The systemic sympathomimetics have the potential to aggravate certain disease states including diabetes, hypertension, heart and thyroid disease. Since sympathomimetics are adrenergics and have adrenalinlike action, they may modify insulin release as well as the breakdown of glycogen to glucose. In nondiabetics, this is of no consequence because they can readily readjust blood sugar levels. In some diabetics, however, sympathomimetics can affect blood sugar levels enough to cause serious problems.

Hypertensive patients have excessively constricted blood vessels. Adding a vasoconstrictive drug into the circulation can worsen the condition.

If a patient has cardiac arrhythmias due to overstimulation by the sympathetic nervous system, these adrenergic agents can exacerbate the problem. There is also an increased chance of anginal attacks in patients with that disease.

Patients with hyperthyroidism may also have problems with sympathomimetics. The additive action of high blood levels of thyroid hormone coupled with exogenous sympathomimetics can cause cardiac arrhythmias.

All of the above are "use with caution" situations, not strict contraindications. The products should be used with caution or under the supervision of a physician. Therefore, manufacturers of OTC products containing systemic sympathomimetics are required to place a warning on the label stating: "Except under the advice of a physician DO NOT take this product if you have high blood pressure, heart disease, diabetes or thyroid disease."

Consumers seeking alternative products for their stuffy nose should be directed to the topical decongestants. They are not appreciably absorbed and do not reach significant systemic blood levels. They, therefore, do not bear the above warning statement.

Another "adverse" effect caused by nasal decongestants is rhinitis medicamentosa (rebound congestion). The consumer may complain that the product currently used no longer affords adequate relief, or that the decongestant action doesn't persist as long as it formerly did. It has been reported that up to five percent of all visits to ear, nose, and throat specialists are for rebound congestion.

The exact mechanism for rebound congestion is not known, but a plausible explanation is that prolonged overconstriction of the blood vessels in the nose induces local submucosal hypoxia (insufficient oxygen). That, in turn, causes hyperemia (excessive blood flow) into the hypoxic area and results in vasodilation. Another theory is that vasoconstrictors possess beta-adrenergic stimulant action along with their predominant alpha-adrenergic activity. The beta effect is not normally pronounced when the drugs are used correctly. When they are used too frequently or for prolonged periods of time, the beta stimulant action becomes more dominant and outlasts the alpha effect. This leads to secondary vasodilation and nasal vessel engorgement.

Rebound congestion can be expected whenever topical decongestants are used longer that 3 to 5 days. It is most prevalent with the short-acting topical agents, less so with the long-acting topicals, and rare with the systemic agents.

The simplest method for treating rebound congestion is to completely withdraw the topical vasoconstrictor. However, patient acceptance of this method is poor because it can result in bilateral vasodilation and total nasal obstruction. A more acceptable method is to discontinue the

medication in one nostril at a time. The patient can continue to use the medication correctly in the other side of the nose until the rebound condition subsides in the drug-free nostril. This normally takes one to two weeks. Withdrawal from the other side of the nose can be undertaken when the first side is clear.

An alternative approach is to substitute a systemic decongestant for the topical agent. The patient can use saline drops or spray during the weaning period. A saline product has the dual function of keeping the nasal mucosa moist, while providing psychological assistance to those individuals who have become dependent on introducing medication into their nose.

Patient motivation and compliance is absolutely essential if the condition is to be relieved. The patient should understand why the condition exists. He should be told that a week or so of discomfort may follow discontinuance of the medication, but that this will gradually decline in severity until there is no further need for continued medication use.

Drug Interactions

The OTC label warning mentioned earlier continues to read: "Do not take this product if you are taking a prescription antihypertensive or antidepressant." This warning refers to a potential interaction between monoamine oxidase inhibitors (MAO) and sympathomimetics, which is considered an absolute contraindication. Since MAO inhibitors decrease the metabolism of sympathomimetics and the neurotransmitters that indirect-acting sympathomimetics release, they can potentiate the activity of the sympathomimetics. Hypertensive crisis has been attributed to this interaction.

Systemic sympathomimetics can also inhibit the action of guanethidine (Ismelin®) and guanadrel (Hylorel®). Concurrent use with either of these agents is not recommended.

Topical decongestants are neither contraindicated nor implicated in any drug interactions.

Topical vs. Systemic Decongestants

The question of which decongered tant is best is based on subjective preference, not scientific factorized Systemically administered productorized are claimed to provide a more effective decongestant action because they reach all parts of the nasopha yngeal and sinus mucosa regardles of the extent of clogging of the naspassages. The introduction of top cally applied drugs may be impeded by severe congestion.

The effect from systemic drugs slower in onset, but supposed more prolonged since topically a plied medication is washed away I the action of respiratory tract fluid However, some topical medication possess a duration of action comprable to the oral dosage forms. Ox metazoline, for example, is report to be active for 6 to 12 hours after a

ministration.

The orally administered dru rarely cause rebound congestion and, therefore, may be preferr when a decongestant is needed longer than 3 to 5 days. Anoth claimed advantage is that the or agents represent a uniform dose a are not reliant on the dexterity of t person using the application utens the amount of solution left in t spray bottle, or the viscosity of t solution. Some proponents of o dosage forms feel that they preve cross contamination between diff ent users, or reinfection of the sa person due to touching the appli tor, inhaler or plastic spray tip to nasal area and picking up infect organisms.

Systemic drug products may car side effects not experienced w topical agents because the system affect tissues other than those of nasal mucosa. Also, topically plied decongestants induce a m prompt and profound vasoconst tion of nasal blood vessels than c agents. This accounts for their sorption being negligible. Thus, s temic reactions following topics applied nasal decongestants are I when these products are used as rected. However, when an excess amount of decongestant solution placed into the nose, it drains i the stomach where is can be sorbed. Most clinical symptoms o inating from topical decongest use are caused when the drugs overused.

Consumer Advice For Topical Decongestants

The correct use of the applicator utensil is most important. As a rule, a nasal spray is preferred over drops because it delivers the medication dispersed into a finer particle size which will penetrate a greater area of the nasal mucosa. The medication is less likely to be swallowed because the particles are smaller and do not flow backward as rapidly. On the average, a single spray will deliver the equivalent of three drops.

Absorption can be minimized when using a spray by keeping the nead upright during and after administration. For the next few minutes, the person should sniff hard. This will allow additional medication to reach further into the nose if congestion still persists. Keeping the nead upright will permit excessive drug to run out of the nose instead of nto the throat and then into the stomach.

When using drops, the individual should recline on a bed with his nead hanging over the edge. He hould remain there for several minutes after the drops have been intilled. Turning the head from side to ide helps distribute the medication of a larger area of the nasal mucosa.

For optimal action, inhalers hould be warmed in the hand before ise. This increases the volatility of he active ingredient and its chance of reaching the affected nasal mucoa. The end of the inhaler should be viped clean after each use and the init should not be shared with other atients.

It is a good idea to keep all medication out of the reach of children, but his is especially important for inhalms. Neither levodesoxyephedrine or propylhexedrine has been found to be safe for use in children under ne age of six. If a child swallows any haler wick, systemic effects are ossible because the active ingredint will be released in the gastroin-

testinal tract and will be absorbed.

The Use of Decongestants in Children. Only nasal decongestants with specific indications and dosage instructions for such use should be administered to children. Drops are generally preferred for children under the age of six because their nostrils are too small to accommodate the spray tip. Also, they will hold still better for the application of drops than for a spray.

Mentholated products are usually safe for adults but their use in children under the age of two should be avoided. In infants and small children, menthol-containing products can cause spasms of the glottis. Asphyxiation has been reported in infants following topical application of menthol-containing preparations.

Contamination. Containers of topical nasal decongestants can become contaminated with bacteria or viruses after improper use. This is minimized if the dropper or spray tip does not touch the nasal passage. If this is not possible, the dropper or spray tip should be rinsed in hot water after each use. Needless to say, no more than one person should be permitted to use the same container. The bottle or spray pack should be discarded after the medication is no longer needed. It should also be discarded if the solution becomes discolored or outdated. The product should be stored in a cool place, since this will retard the growth of organisms inadvertently introduced into the container.

Summary

Used correctly, nasal decongestants are safe and effective for self-medication in alleviating mild nasal congestion (stuffy nose). The FDA Advisory Panel on OTC Decongestants has published consumer advice for their proper use. It is summarized in Table 3.

TABLE 3 Basic Consumer Advice for Nasal Decongestants

Topical Products

- Do not use this product for longer than 3 to 5 days unless a physician directs otherwise.
- This product should only be used by one family member, to minimize the chance for contamination.
- Do not administer to children under the age specifically noted on the label.
- Keep this medication out of reach of children.
- Keep this product tightly closed and in its original container. Do not refill spray containers from a stock package.
- Do not touch the nose or other tissue areas with the spray tip or dropper.
- Do not use this product if the solution has turned brown, or developed an odor.
- A drop form is preferred over a spray for children, due to their small nasal openings.
- Do not exceed recommended dosage.
 To do so may cause symptoms such as sneezing, burning, stinging, or an increase in nasal discharge.

Systemic Medication

- Do not exceed recommended doses in order to avoid symptoms such as nervousness, dizziness, and sleeplessness.
- If symptoms persist longer than seven days, get worse, or are accompanied by a high fever, consult a physician before continuing use.
- Do not take this preparation if you have high blood pressure, diabetes, heart disease or thyroid disease except under the advice and supervision of a physician.
- Do not take this preparation if you are presently taking a prescribed antihypertensive and antidepressant drug containing a monoamine oxidase inhibitor, except under the advice and supervision of a physician.



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Thanks, Albany College of Pharmacy

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The Community Pharmacist and High Blood Pressure

Phillip Weiner, P.D.
Chairman MPhA Public Affairs Committee

Ben, that is the name I will call him, was referred to my Pharmacy because of the services we provided at the time he needed them. One of the medications he was on was Furosemide. We used the brand name because that is what was called for on the prescription. At that time, the generic drug was not discussed. After a number of months had passed and Ben was feeling better, he and his wife decided they could get the drugs cheaper at the discount drug store. And so they could and so they did. However, a couple of months later, Ben found himself in the hospital. It seems that the generic drug was dispensed. When he came out of the hospital this time, he again came back to my Pharmacy. We were able to obtain the brand name drug for Ben from the manufacturer to see if he would stay stabilized. So far he has. Many questions can be raised from this story. Would his hospitalization have happened if he had stayed our patient? I cannot say for sure. If I had been asked to substitute a generic drug would the same episode have occurred? Possibly, but I do not think so. I do not think so in this case because the generic furosemide I use is from a major manufacturer also. Nevertheless, Ben came back to us. Will he get better care? I believe so, and you will see why as I go along.

Back when I was a young Pharmacist, I was taught that high blood pressure is anything about 120/80 plus 1 on the systolic above age 40. Therefore, a 50-year old patient with 130/80 was ok or a 70-year old with 150/80 was ok. Today, like most things, is different. Today, we know that the diastolic reading is probably more important than the systolic reading—as the deciding factor in to treat or not to treat.

I am not here today to tell you what high blood pressure is but rather to address the Pharmacist's role in high blood pressure control. Pharmacy is unique in education. Not all Pharmacists have the same training. Back when I started my Pharmacy School work, now called didactic training, education in high blood pressure was relatively unknown. Most of what I know, and it is also true of the Pharmacists of my generation and before, has been gained through self-study, continuing education, and experiential, anecdotal episodes. Today's Pharmacist B.S. graduate has had didactic edu-

cation in physiology, pathophysiology, pharmacology, and therapeutics of hypertension. Their direct patient care training is done either in inpatient and/or outpatient clinical setting with medical problems including hypertension. All students, both Pharm. B.S. and Pharm. D. are certified by the American Heart Association to take blood pressures. The Pharm D, in addition to the aforementioned course work for the Pharm B.S., has their load intensified to meet their increased needs to provide direct patient care for monitoring patients with hypertension and to recommend possible medication regiments to other health care personnel, particularly in difficult cases such as resistant hypertension.

Continuing education programs are available to Pharmacists locally, nationally, and internationally—at Pharmacy School, at conventions, in motel meeting rooms, and in other reasonable areas. The programs are conducted by the full scope of health professionals and most certainly by Pharmacists for Pharmacists. This program today is not the first I have presented. The Doctors of Pharmacy associated with the School of Pharmacy are frequently invited to speak to both professionals and lay groups about all topics concerning Pharmacy and drugs.

Now, where does Pharmacy get its authority to screen patients for high blood pressure or to monitor their compliance or for that matter where is the authority to do anything but count and pour, lick and stick, type or gripe? Simply stated, this authority comes from the Maryland Pharmacy Act, Section 12—101 (J); and I quote: Practive Pharmacy means to engage in any of the following activities:

- 1. Selecting, preparing, and dispensing drugs, medicines, or devices
- Providing information and explanation to patients and health care practitioners about safe and effective use of drugs, medicines, or devices, or
- 3. Identifying and appraising problems concerning the use or monitoring of drug therapy.

Going over the three subheadings again, 1 to select the appropriate brand of drug if the prescription is written in the generic or the patient requests a generic or the State formulary requires a generic to be dispensed . . . preparing allows pharmacists to extemporaneously prepare capsules, ointments, lotions, solutions etc. Without this ability, Bromptons mixture could not legally be made and for that matter neither could

This speech was delivered as part of a High Blood Pressure workshop at Provident Hospital.

MOM and Cascara. Dispensing simply means the giving of the prescription to the patient after the prescription has been read, the proper drug selected, the appropriate information placed on the label and the prescription itself, the instructions given to the patient and the proper amount of drug counted or poured or whatever . . . not so simple.

The providing of information and explanation is the crux of not only my talk today but the major role of the Pharmacist today in progressive hospital settings and in service oriented professional Pharmacies such as mine. I will, of course, talk more on this subject as I go along. The third subheading is identifying and appraising; here is where we interact with other health professionals by inputting our knowledge of the drugs and patients we come in contact with. Therefore, Pharmacy does have a legal basis for its professional activities. Pharmacists have been trained and educated not only to provide the prescription drug product prescribed by the Physician, but to advise and consult with the patient to identify potential problems such as drug interactions, noncompliance, lack of drug efficacy, and the possibility of drug toxicity. We have the right, but much more important, we feel we have the obligation. From my experiences in my Pharmacy, I will give some examples of problems we have seen with high blood pressure medications. Prazosin can cause postural hypertension, therefore, the patient should be advised to take the first dose at bedtime and to arise from a prone position to a sitting one before standing up. I have had my patients complain of a lack of sex drive after being placed on high blood pressure medication. If this occurs and if the medication is the cause, the medication can possibly be changed, doses lowered, or at a minimum, the patient must be counseled that the medication is necessary to sustain a quality of life. Therefore, it must be taken as directed. It is the obligation of all health professionals to counsel, and here is one area of great psychological need. The most important area I try to counsel patients in my Pharmacy is the newly diagnosed and/or poor compliant hypertension patients. There are so many factors that come into play such as race, color, national origin, smoking, sex, age, level of understanding, sight. hearing, ability to read; and I am sure if I poll you we can come up with dozens more. But suffice it to say there are many. Before I discuss some of the factors individually let me answer the larger question of— What is the Pharmacist Doing to Monitor Hypertension Patients?

Certainly, screening is at the top of the list. In some Pharmacies, screening programs are conducted by the Pharmacists themselves, by other trained health professionals, or pharmacy students. In others, electronic high blood pressure reading machines are available to the public to use at little or no charge; but I am not in favor of them unless they are under the direct supervision of a Pharmacist who can interpret the readings and counsel the patient accordingly.

Dr. Donald Fedder, Director of the Community

Pharmacy Program, University of Maryland, School of Pharmacy in Baltimore, conducted a 3-year program thru the National Heart, Lung, and Blood Institute to demonstrate the impact of Statewide coordination of high blood pressure control on control success and reduction of mortality for high blood pressure diseases. Dr. Fedder, writing in his article, High Blood Pressure and the Pharmacy, Contemporary Pharmacy stated: "Traditionally, the first point of contact of the hypertensive patient and pharmacist is after a diagnosis has been made and a drug has been prescribed. Focusing on this interface, what can Pharmacy do to impact on high blood pressure control? If we accept that patient plus drug plus time equal control, Pharmacy efforts should be directed most profitably to the following areas:

- 1. The purposeful communication and assessment of patient understanding of drug knowledge.
- 2. Assessment of drug taking behavior, with added reinforcement as required.
- 3. Patient follow up; using methods such as outreach and "tickler file" reminders of refills due to assure intelligent compliance.
- 4. Monitoring for effect of treatment; and
- 5. Feedback to the Physician.

Another study "The effect of Pharmacist drug monitoring and patient education on hypertension patients by McKenny et al proved what Dr. Fedder's program was doing. It was a study conducted in six Pharmacies throughout the State of Virginia to determine whether community Pharmacists could be trained effectively to provide drug monitoring and educational services and whether these services increase compliance and therapeutic control in hypertension patients. In preparation for the study, participating Pharmacists received selfinstruction and were given the opportunity to attend a hypertension clinic. Audiovisual programs, booklets, and verbal consultation were used in patient education. The results showed better compliance in the study patients (44 of 70) than in the control patients (23 of 66). Better control was achieved in 74 percent of study patients and 58 percent of control patients.

I started in Dr. Fedder's program utilizing the "tickler file" for over 1 year. At that time, I evaluated the system as to my Pharmacy and found that other than the sending of postcard reminders, I was paralleling the program's ideals. I am constantly on the lookout for noncompliance when I refill a prescription. I usually speak with each patient about their medicines. When noncompliance occurs, I try to find out the reason and counsel the person as to why he or she should comply. I remember one patient who was taking 3 medications: 2 for high blood pressure—a beta blocker and methyldopa, and the third for diabetes. He would receive 100 doses of each to be taken t.i.d.—each dispensed in original containers. Therefore, by simple division, the medications should have lasted 33 days. He constantly and

consistantly ran 38 to 40 days over a 2-year period. Each time I would refill his prescriptions, I would take a Julian calender to the window, show him when he had his last refill, show him the day for that date and the present, subtract the two with the resultant 38 to 40 difference between the dates and explain to him that the medication should have only lasted 33 days. He just as consistently explained the difference by telling me that he had a few tablets left over from the last refill. I never could get him to admit he was missing at least 10 percent of his doses or comply. He was a compliance failure.

Early in my Pharmacy life when I would counsel a newly diagnosed black patient, salt was the biggest problem. How could we persuade people who loved the salt shaker to ease up and off? This is a success story. Today, I find more and more people, in general, and blacks, in particular, who do not use extra salt. In a paper presented before the Economics and Administrative Sciences Section of the APHA Academy of Pharmaceutical Sciences, Banahan and Sharp, a screening program in Mississippi to identify previously undiagnosed hypertension patients and to refer them to physicians for evaluation and treatment was set up. The results of that program were significant over a control group. The program involved patient education and patient involvement. This is a compliance success story, not only for you and me but, most certainly for the patient.

Part of hypertension screening, hypertension monitoring, and compliance monitoring has to do with patient education. All education is important. We would not be here today if continuing education was not important; but patient education is the focus for us. Just think of the joy you have received when you counseled a patient, the patient complied, and positive results occurred. That has happened to all of us, just as the I told you so thoughts enter our minds when we see or read our patient education failures. I will pass on to you a trick saying I have used on newly diagnosed hypertension patients who are usually started on diuretic medications. I take the prescription from them, read it to myself, and fill in verbally or quietly whatever information is missing from the written prescription while still standing at the window. I tell the patient that I want to talk to him or her when I finish filling the prescription. The time it takes to fill the prescription I hope is used by the patient to wonder what I want to say. In other words, I am priming the pump. When I return to the window with the filled prescription, I ask the patient if he or she has ever heard of the Fram Oil Filter Commercial on television? You know, it is the one where a mechanic is standing in front of the camera while a car is being towed into his garage, and the mechanic says to the audience something like "I told him to change his oil and filter at reasonable times and it would save him money in the long run; but he didn't listen. Now he has a major repair bill coming. I told him pay me now or pay me later." I pause for a second or so and

then explain the corollary this way. The medication I am dispensing to you costs between 5 and 15 cents a day. If you take one a day—day in and day out without missing a dose, reduce your salt intake, eat properly, get sufficient exercise, and follow your physician's instructions, you can live a long and healthy life both qualitatively and quantitatively in most cases, and not need further medications for possibly years to come. BUT if you continue on the way you have and not take care of yourself, you are looking at the possibility of dire consequences. A stroke perhaps if you live and if you are not a vegetable in a nursing home. You will certainly pay me later. The 5 to 15 cents today will be transformed into 3-4-5 or more dollars a day in medicines. So . . . pay me now or pay me later. I have found this works. I get the patients' attention and give them a story to remember.

The last area the Pharmacists are helping to monitor hypertension patients is in the area of toxicity. Frequently, side effects are brought to our attention on subsequent refills by the patients who think that whatever is occurring is normal or by those patients who would not bother the doctor. Examples of possibly toxic side effects are the dizziness produced by prazosin, joint discomfort of hydralazine, and orthostatic hypotension of captopril. We can help determine if the complaint is or is not drug induced and provide a solution to deal with toxicity by dose or drug change or inform that the problem will go away on its own.

Now, how can we help you? Simply, just ask . . . whether you need information on drug names, strengths, dosages, side effects, contraindications, whatever, call us . . . call us for patient information. Within the next decade, probably 90 percent of all Pharmacies will have computers. In my Pharmacy, I can call up at least 18 months of drug profiles for each patient which will include possible drug interactions. Call us for information on OTC drugs. Did you know that Pharmacists are the only people legally allowed to disseminate information on OTC drugs in a Pharmacy? Again, we have the knowledge and the skills to help you, call us. Oh yes, remember too, when we call you, listen to us. We probably see the patient more often than you do and more often than the physician does. Pharmacists are the most visible and most available health professionals in the community. In my Fram oil filter speech to the patient, if I know the physician and, therefore, know what he or she would have told the patient, I reenforce that information and wait for a response. This also helps the patient remember.

The sum of the parts is for all health professionals to join in battle against the disease states of the patient. We all can do it together. But remember . . . call me now or call me later, but call me.



New Guidelines for High Blood Pressure Therapy

The new guidelines for high blood pressure therapy are being implemented in Maryland through the leadership and coordination of the Maryland High Blood Pressure Commission. The new guidelines contained in the 1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC III) differs substantially from its predecessor, which was published in 1980.

The JNC III recommendations include modifications and recommendations for detecting and evaluating high blood pressure (HBP), a change in rationale for treating mild hypertension, revision in the step-care approach to therapy, use of nonpharmacologic therapies, management in special groups, and education for control and prevention.

The report recommends referral of adults (age 18 and older) with an average blood pressure (three mea-

surements at each sitting) of 140/90 or greater to a source of medical care for diagnosis and treatment of HBP. This new referral level represents a lowering of the former Maryland Referral Standard from 150/90 to 140/90. Copies of the new "Maryland Standards for the Referral of Persons with Elevated Blood Pressure to a Source of Medical Care" may be obtained from:

Maryland High Blood Pressure Commission 201 West Preston Street Baltimore, Maryland 21201

The medical care community (practicing physicians, nurses, pharmacists, dentists, optometrists and other health professionals) is urged to use the new standards in handling referrals and in diagnosing and treating HBP.

MARYLAND STANDARDS FOR THE REFERRAL OF PERSONS WITH ELEVATED BLOOD PRESSURE TO A SOURCE OF MEDICAL CARE*

Blood pressure referrals should be determined by taking the average of three measurements at each sitting.

ADULTS (Age 18 and older) Use fifth phase of Korotkoff sounds for diastolic BP.

Systolic Blood

Diastolic Blood Pressure (mm Hg)	Recommended Follow-up**
< 85	Recheck within 2 years
85 to 89	Recheck within 1 year
90 to 104	Confirm promptly (not to exceed 2 months)
105 to 114	Evaluate or refer promptly to source of care (not to exceed 2 weeks)
<u>≥</u> 115	Evaluate or refer immediately to a source of care

ressure (mm Hg) /hen DBP : 90 mm Hg:	Recommended Follow-up**	
< 140	Recheck within 2 years	
140 to 199	Confirm promptly (not to exceed 2 months)	
<u>≥</u> 200	Evaluate or refer promptly to source of care (not to exceed 2 weeks)	

**If recommendations for follow-up of DBP and SBP are different, the shorter recommended time period supersedes, and a referral supersedes a recheck recommendation.

PLEASE NOTE THAT THE STANDARDS LISTED ABOVE ARE FOR REFERRAL ONLY AND ARE NOT INTENDED TO SERVE AS STANDARDS FOR THE DIAGNOSIS AND TREATMENT OF HIGH BLOOD PRESSURE.

The use of the standardized measurement technique, as well as properly calibrated instruments and appropriate cuff sizes, is necessary to ensure comparability of blood pressure readings with the above standards.



These standards for referral have been endorsed by the Maryland High Blood Pressure Commission and the American Heart Association, Maryland Affiliate, Inc.

* FROM THE 1984 REPORT OF THE JOINT NATIONAL COMMITTEE ON DETECTION, EVALUATION, AND TREATMENT OF HIGH BLOOD PRESSURE.



The Maryland High Blood Pressure Commission endorses the HBP provider courses offered by the American Heart Association-Maryland Affiliate, Inc. and the Center for Health Education.

Maryland High Blood Pressure Commission 201 West Preston Street Baltimore, Maryland 21201 American Heart Association-Maryland Affiliate, Inc. 415 N. Charles Street P.O. Box 17025 Baltimore, Maryland 21203 (301) 685-7074 Center for Health Education Coggins Building 1204 Maryland Avenue Baltimore, Maryland 21201 (301) 837-2705

NOVEMBER, 1985 (

^{*} FROM THE 1984 REPORT OF THE JOINT NATIONAL COMMITTEE ON DETECTION, EVALUATION, AND TREATMENT OF HIGH BLOOD PRESSURE.

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Pharmacy in the 21st Century

(continued from the October Issue)

Alternative Futures III: Pharmacology and Pharmacy

On the second morning, the conference shifted to more pharmaceutical-oriented presentations. Dr. William Check, President of Medical and Scientific Communications, Inc., provided an overview of drugs and drug delivery systems of the future. According to British pharmaceutical expert George Teeling Smith, the second pharmacological revolution will be based on unraveling the chemistry of human physiology. Three classes of therapies that may come out of this research will be immunomodulators, prostaglandin synthesis modifiers, and therapies based on genetic engineering techniques. Immunomodulators may be helpful in combating immune deficiency diseases, such as the AIDS epidemic. Modification of specific products of the prostaglandin pathway could heal or prevent gastric ulcers, heart attacks, and clotting disorders.

Genetic engineering is already providing several medically useful chemicals, including human insulin, human growth hormone, and the immunomodulator interleukin-2. In addition, these techniques may generate the means to deliver gene replacement therapies for persons born with some inherited diseases. When combined with newly emerging information about the role of oncogenes in causing cancer, genetic engineering could prevent formation of some cancers.

The new drugs will also be delivered in novel ways. Examples include the already marketed osmotic pump tablet, controlled-release systems based on biodegradable polymers, magnetically activated spheres, and transdermal delivery systems.

The role of the pharmacist may well be enhanced in this high-tech world, said Check. Formulation, dispensing, and monitoring of the new drug dosages will require increased training. And counseling of patients, a function that pharmacists already provide in many locales, is likely to take on new importance.

An "optimistic" view of drug distribution in the next century was presented by Lawrence Hoff, then Executive Vice President of the Upjohn Company. Factors forcing change include more consumer involvement, increasing pharmaceutical competition, greater knowledge of individual metabolism, and enhanced roles for non-medical persons as decision-makers. Home health care will also become more prominent, with implications for the monitoring of doses and adverse effects. Delivery of drug information for these patients may well be via a retail outlet, possibly controlled by a hospital. Hoff also sees a rise in a new category of prescribers, fueled by many switches in prescription drugs to over-the-counter (OTC) availability.

Medicine will become more sophisticated, complex and technologically oriented, said Dr. Richard Crout, then Director of the National Institutes of Health's Of-

fice of Medical Applications of Research. Crout noted a commonality within the scenarios:

- Continued high technology;
- Great demand for health care;
- Prevention: postpones troubles but doesn't eliminate them;
- Pharmacists must be scientists first if they are to compete successfully.

Science is the bedrock of pharmacy, so pharmacy schools will need to train students in science even more than today, Crout said. In addition, the demand for health care will increase, as will the proportion of the Gross National Product devoted to health care and to health-related research and development. However, Crout does not see elimination of disease: rather post-ponement of morbidity through prevention and wellness strategies and better ameliorative care.

He suggested that the most competitive strategies for pharmacists will be not to increase their numbers, but to graduate more doctor of pharmacy (Pharm. D.) students with increased technological knowledge, and to work in groups that deliver high-tech medicine. In this scenario, the pharmacist's chief competition may well be the scientifically trained research doctor of philosophy (Ph.D.).

In his view, personal counseling will not be a major role; too much information will be available on T.V. and computers.

Dr. Jere Goyan, Dean of the University of California, San Francisco, School of Pharmacy, also sees an increased demand for technologically sophisticated pharmacy education. In the future he considers most likely, drugs will be individualized and many prescription products will go OTC. But he sees these changes creating a need for medication couselors, a niche pharmacists could fill. Computers, Goyan feels, will not be able to counsel "at the level of the average fifthgrader," as pharmacists now do.

Another trend mandating more complex education will be a role for pharmacists as "therapeuticians" following physician diagnosis. Pharmacy schools will perform more research, there will be more pharmacy specialities, and education will be competency-based.

In all scenarios there will be turf battles between pharmacists and physicians, said Virginia Commonwealth University Health Economics Professor Louis F. Rossiter. But in what he viewed as the most likely scenario—continued growth—increased use of technologically advanced medicine and stronger demand for dispensing will mean an increase in pharmacists, especially Pharm. D.'s. An expanded information and counseling role will follow from the greater variety of drugs and intense marketing.

Rossiter suggested that innovative healthcare pro-

grams for elderly people in South Florida might be "a microcosm of the future." In these government-subsidized demonstration projects, designed to hold down costs, pharmacists are being given an expanded role.

Pharmacists' Projections

Following the formal presentation of ideas about the future context of pharmacy, the pharmacists were organized into four groups, each of which considered one scenario for the future. Under the assumptions of the assigned scenario, each group was to answer several questions:

- What would be the major changes in society and health care that would effect drug use?
- Where would dispensing be done?
- What tasks would pharmacists do? How many pharmacists will there be and what extent of education and training will they have?

Below are some of the highlights of those group discussions.

The *Continued Growth* group foresaw a more educated public that would have access to greatly expanded medical databases and would also seek more professional care. Patient care would take place at short-stay critical hospitals, extended-care facilities, and ambulatory sites at which multiple medical services would be available—so-called medical supermarkets.

Drugs would be dispensed in these medical supermarkets. There will be some increase in chain store activity, but few independent pharmacies. Pharmacy personnel will increase by about five percent by 2010, and professionals will predominate: the fraction of pharmacists having a Pharm.D. degree will rise from six percent in 1982 to 40 percent in 2010. The increase in more-educated pharmacists will arise from the new high-technology nature of drugs and drug dosage forms. The primary role for pharmacists will be monitoring patients, which will be due to the greater array of OTC drugs and the more sophisticated nature of new drug delivery forms.

The *Decline and Stagnation* group foresaw a society faced with a worsening environment, chronic unemployment, increasing poverty, and a more stressful life. The need for medical care increases, while its availability decreases. Most medical care takes place in group-care settings, such as HMO's. Self-care, non-traditional practitioners, and folk remedies proliferate. Independent pharmacies do not do well; they go back to the "calamine and peroxide" era. Large centralized dispensing sites predominate; OTC's become more common. In 2010 pharmacists will still do considerable dispensing, but the drugs will be older ones, such as cimetidine, penicillin, and antihypertensives.

In the *Disciplined Society*, largely centralized, lowtech pharmaceutical services will depend heavily on pharmacists. All health care services will be linked to a centralized database by computers. Most drugs will be older agents with proven safety. And 80 percent of drug sales will be OTC. Pharmacists will work primarily in the federal health network. They will use many aids and technicians and will initiate and monitor therapy. A minority of highly trained pharmacists will handle high-tech medication in a few tertiary acute-care centers.

In the Transformational Society a vastly different array of changes was envisioned. The highly decentralized medical system would consist of a heterogeneous mixture of high-tech therapy available at special centers, wellness and health promotion practiced by individuals (major costs of which would be paid for by "Life Enhancement Insurance"), and social support through a wide network of friends, families and spiritual groups. More educated and informed consumers would consult their home computer to help with diagnosis and drug therapy. Home computers would also perform daily or periodic personal biochemical analysis and recommend appropriate diets and supplements. There will be "pharmacy boutiques," a new generation of independent retail pharmacies providing customer services at premium prices.

Many drugs would be available OTC. Especially popular would be the herbal remedies commonly available in supermarkets and pharmacies.

Pharmacists would keep track of drug use and wellness states by telecommunication devices and counsel individuals after monitoring their physiology. Pharmacists would fall into three major groups, depending on their emphasis:

- Pharmacotherapists and counseling pharmacists would devise and adjust doses (directly with the patient or through physicians) and monitor outcomes.
- Pharmaceutists would formulate medicines, including patient-specific medicines such as immunomodulators and vaccines, using specialized technologies.
- Pharmacoherbalists, specializing in pharmacognosy, would be popular with customers but have low prestige among their high-tech peers.

There would be relatively few pharmacy aids, and routine tasks would be performed by computers and robots.

Most Likely Forecasts

Following presentation of the conclusions from the small-group scenario discussions, conference participants voted on the estimated likelihood of the four scenarios. The Continued Growth option was thought to have a 46 percent chance of occurring. The Disciplined Society, Transformation, and a mixed scenario composed mostly of features from the Continued Growth and Transformation formats each had about a 15 percent chance of occurring. The Decline and Stagnation future was thought to have only an eight percent likelihood.

Clement Bezold commented that, when compared

to other health providers and to corporate executives, the pharmacists came down somewhat more heavily in favor of Continued Growth and were more skeptical of the Transformation alternative.

Certain anticipated trends emerged from the discussion of the four "futures" scenarios.

Major factors influcencing pharmaceutical use in 2010 included an increasingly elderly population, more widespread health promotion and wellness activities, more vigorous efforts at proving the cost-effectiveness of drugs, a decline in health-care expenditures as a proportion of GNP, and an increase in home remedies and nonconventional therapies.

More sophisticated drug delivery systems were foreseen by many, including more prevalent transdermal, aerosol, and pump systems and increasing reliance on controlled-release devices. There was some agreement that delivery systems would have to pass a cost-effectiveness trial before marketing approval.

One important feeling expressed by several speakers and meeting participants was difficulty accepting the transformation scenario. Perhaps it is understandable that to most persons the continued growth option was more likely, since the future most easily visualized is an extrapolation of the present. But objections were raised to many specific features of the transformation scenario, for instance, the development of computers capable of replacing doctors; discovery of true cures for cancer or heart disease; and growth of healthy lifestyles and wellness habits from temporary trends into a major force in health maintenance. On the other hand, several speakers argued that current trends are already impelling the system in that direction.

Another common thread emerging from the scenario discussions was the belief that a large proportion of prescription drugs would be moved into the OTC category during the next few decades. Some observers postulated a trial period in which prescription durgs entered a third class until their futher safety was established. But more were assumed to qualify for general OTC sale.

Finally, the participants expressed a strong feeling that pharmacists of the next century will play an important role in monitoring medications, and, while there will be some opportunities for independents, most pharmacists will practice in settings that are part of megahealth care enterprises or retail chain pharmacies.

Conclusion

At the conclusion of the meeting, individuals from the sponsoring pharmacy organizations expressed their opinions on the Conference and its implications for the profession. There was a general consensus that the Conference, with its explicit focus on a range of plausible futures, had been an important first step in defining the environment for pharmacy in the 21st Century: a first step that must be followed up in a variety of ways, including repeating this type of broad environmental scanning and forecasting effort at periodic intervals,

possibly every five years. In addtion, it was felt that the participants and their organizations should review in detail the papers and the results of the exercises and consider the implications for their area of pharmacy or health care practice.

For the professional groups, the range of players shaping the future suggests that subsequent discussion of this type should be done with consumer groups, the range of players shaping the future suggests that subsequent discussion of this type should be done with consumer groups, since they will be the ultimate determinant of the direction of the health care market, including the types of pharmacy services which are sought. Simultaneously, pharmacy groups, in addition to continuing the dialogue among themselves, need to share this planning exploration with other health care provider groups, policy-makers, and pharmaceutical manufacturers.

The uncertainty of the future and the broad scope of the changes it may bring also argues that individual pharmacists need to go through a similar process in reflecting on their own career choices. This should be delivered both through the various professional groups to their members and through the colleges of pharmacy.

Dear Dave:

The monthly meetings of the Maryland Society of Hospital Pharmacists will be on the following Thursday evenings.

September 12	Good Samaritan Hospital
October 10	Saint Joseph's Hospital
November 14	University of Maryland Hospital
December 5	To Be Announced
January 9	To Be Announced
February 13	To Be Announced
March 13	To Be Announced
April 10	To Be Announced
May 8	To Be Announced

The program format is traditionally cocktails at 6 PM, dinner at 7 PM followed by a short business meeting then the presentation with completion by 9:30 PM.

The Annual Seminar is scheduled for June 20–22, 1986 at Ocean City.

As additional information becomes available I will forward it to you.

Dear Dave:

This is just a short note from Kappa Psi to say "thanks" so much for letting us use the Kelly Building this time and all the other innumerous times that we have used it.

Thanks for being so considerate to our fraternity.

Please let us know if we fail to leave it in acceptable conditions.

We hope to maintain an amiable relationship between Kappa Psi and the Maryland Pharmaceutical Association in the future.

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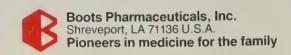
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And that's what we expect from the men and women of our 1985 Pharmacy Consultant Panel.

Advice on what we're doing right and what we're doing wrong. And how to make things better.

Points of view based on their personal experience in pharmacy. Wisdom that will help us help you serve the public better.

Problem solving starts with listening.

We hope these pharmacists will give us an earful.



Meet our 1985 Pharmacy Consultant Panel.

Standing Left to Right:

John Piecoro, Jr., Pharm. D. Clinical Pharmacist University of Kentucky Lexington, Kentucky

Seated Left to Right:

Charles Lippert, R.Ph. Community Pharmacist Zeeland, Michigan Reed Rosting, R.Ph. Vice President, Hospital Sales Bergen Brunswig Drug Co. Orange, California

William Thien, R.Ph.
Director, Health Services &
Pharmacy Operations
Walgreen Drug Stores
Deerfield, Illinois

Carl Lyons, R.Ph. Institutional Pharmacist Tulsa, Oklahoma

John Kogut, R.Ph. Vice President Fay's Drug Company Liverpool, New York Larry Braden, R.Ph. Executive Vice President Georgia Pharmaceutical Association Atlanta, Georgia

Lonnie Hollingsworth, R.Ph. Community Pharmacial Lubbock, Texas Marily Rhudy, R.Ph. Community Pharmacist Topeka, Kansas

Bernard Mehl, R.Ph. Director of Pharmacy Mount Sinai Hospital New York, New York

Not pictured: John Colsizzi, Ph.D., Dean, College of Pharmacy, Rutgers University, Recottency, New Jersey

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L. Wamble, R.Ph. Osceola, Arkansas



R. Holiman, R.Ph. Springdale, Arkansas



J. Kaufman, R.Ph. Sacramento, California



B. C. Adams, Jr., R.Ph. Thomaston, Georgia



D. A. Sciortino, R.Ph. New Orleans, Louisiana



P. Dumouchel, R.Ph. Wellesley, Massachusetts



G. R. Krieger, R.Ph. Redford, Michigan



A. A. Haugdahl, R.Ph. Wayzata, Minnesota



K. L. Corazza, R.Ph. Albuquerque, New Mexico



D. McAndrew, R.Ph. Syracuse, New York



V. J. Moreno, R.Ph. Pawling, New York



S. L. Neuber, R.Ph. Maumee, Ohio



J. Harrison, Pharm. D. Norwalk, California



G. E. Peterson, Pharm.D. Long Beach, California

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W. A. Fitzpatrick, R.Ph.
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M. Rubin, R.Ph. San Antonio, Texas

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THIS AND THAT ABOUT PHARMACY

by Leon Weiner, P.D.

A TRIP TO SEE THE VEEP

Spotlight on Bernie Heyman, P.D.

During the first weekend of August 1985, my wife and I had a delightful trip to Toledo, Ohio where we visited Bernie Heyman, P.D., and his gracious wife, Harriet. Toledo is a great place to tour. It has many beautiful homes, large stately trees, friendly people and also a small version of Baltimore's Inner Harbor, called Portside which was also built by Rouse.

Bernie Heyman, UofMD 1957, moved to Toledo two years ago when he became a Vice President for Lane Drug. Before that, he was one of the partner owners of the Action Drug group in Baltimore. Previous to that, Dr. Heyman was with the Read Drug and Chemical Company after graduating from Pharmacy School. He worked his way up from pharmacist to Director of Merchandising for them. Bernie worked for Read's for 26 years and during that period, he also was Vice President for Thrifty Wise Company.

Harriet and Bernie have three children. They are:

- 1. Michael, who recently graduated from York College of Pennsylvania, and is a computer programmer in Harrisburg, PA.
- 2. Marc, who is in his junior year at the University of Toledo and is majoring in accounting.
- 3. Lisa, who is a sophmore at Worthview High School in Toledo.

Bernie has a younger brother, Irwin, who graduated from the University of Maryland, School of Pharmacy in 1963 and also received his Ph.D. degree from the same school. Irwin worked for Abbott Laboratories for 12 years before recently becoming a Vice President for Syntex Laboratory in Palo Alto, California. Bernie also has two brothers-in-law who are active in pharmacy circles. They are Hillel Aarons, UofMD Pharmacy 1953, who used to own Hertz Pharmacy and at the present time is working for Giant Food and Drug Company. The other brother-in-law is Joseph Meyerowitz who has been a sales manager for Loewy Drug Company for seven years. Prior to that, he was doing the same job for Gilpin Drug Company.

PHARMACISTS IN THE NEWS

Arnold Clayman, P.D., graduated from the UofMD Pharmacy School in 1973. At the present time, he is a pharmacist at Home Nutritional Support Pharmacy, 10200 Old Columbia Road, Columbia, MD in Howard County.



Above Bernie Heyman and his wife, Harriet celebrate their 25th wedding anniversary in their home in Toledo, Ohio.

When Arnie is not working, he finds time to participate with the Liberty Showcase Theatre (LST). The LST is a non-profit program of the Liberty Road Recreation and Parks Council and has as its primary purpose to provide a recreational outlet in the form of theatre activities for area residents. In August 1985, Arnie and his sister, Andrea "Andy" Clayman played the leading support roles in the musical "Brigadoon". Actually, Dr. Clayman was one of the two co-producers of this play, but was drafted into the acting role after another actor backed out because of sudden wedding plans. The play was presented at the Randallstown High School.

David Glenn Miller, P.D., has been named Assistant Director for Professional Affairs for the National Association of Retail Druggists in Alexandria, VA. A 1985 graduate of the UofMD Pharmacy School, Dr. Miller is a member of the Maryland Society of Hospital Pharmacists, Maryland Pharmaceutical Association, NARD student member and UMAB Student Government Alliance.

Pharmacist Arnold Alperstein and wife, Margee, announce the Bar Mitzvah of their son, Gary. A graduate of the UofMD Pharmacy School 1970, Dr. Alperstein is currently working at the Revco Drug Stores.

Because of President Reagan's recent colon surgery, much has been said and read about the subject. A large article in one of Baltimore's newspapers revealed that pharmacist John Magiros, UofMD Pharmacy 1945, also had the same problem. About 2½ years ago, he had two tumors removed from his colon and so far there has been no recurrence of the disease. Everyone wishes John the best of luck and hopes everything works out. Dr. Magiros is the pharmacist-owner of Magiros Pharmacy located in the Village Green Shopping Center in Ellicott City, MD.

Marty Mintz, P.D., is the popular owner of the Nothern Pharmacy on Harford Road in Baltimore. A graduate of the UofMD Pharmacy 1965, Dr. Mintz is not one to pull his punches. For example, in the July Sunday Sun paper, he advertised: "Pharmacist; full time. Must be willing to pamper patients and customers, etc." According to a reliable source, Dr. Mintz was associated with the Baltimore Colts (pre-Robert Irsay days) at one time and we would love to pass on this story.

CONGRATULATIONS TO:

SHEILA DERMAN, P.D., and her husband Paul, on the Bar Mitzvah on their son, Jason, on May 18, 1985. A 1963 graduate of Medical College of Virginia, Sheila is employed by the Rite Aid Drug Company. She is very active in different groups in the Baltimore area including the Baltimore Jewish Council which she was recently elected Treasurer for 1984–1985.

EMANUEL RICHMAN, P.D., on being promoted to Vice-President, Pharmacy Operations, Giant Food, Inc. A graduate of the UofMD Pharmacy 1956, Manny is the son-in-law of Bernard Cherry, UofMD Pharmacy 1936, who is the owner of Cherry's Prescription Pharmacy, Inc. in Baltimore. His brother, Morton David Richman, UofMD Pharmacy 1960, is also employed by Giant Food, Inc.

LEO SIROTA, P.D., on his great help in putting the Baltimore City College of Alumni Association, Inc. on the right track. Dr. Sirota, UofMD Pharmacy 1951, is the Treasurer of the BCCAA which is once again an active group after years of dormancy. He is a pharmacist for Beltway Pharmacy in Baltimore County.

JUNE SHAW, P.D., and her husband Frank who received his high school diploma at the age of 82. Dr. Shaw, Uof MD Pharmacy 1949, has been the head pharmacist at the South Baltimore General Hospital for many years. Her brother is Colen Heinritz, UofMD Pharmacy 1958, who went on and became a physician. Frank's efforts and life story were featured in the Baltimore Morning Sun recently.

ARNOLD L. KAPLAN, P.D., who won a fishing contest when he caught a 23 pound Drum on the Chesapeake Bay this past summer. As a reward, he received a big trophy and a free round trip to anywhere World Airways flies, including Hawaii. A graduate of the UofMD Pharmacy 1973, Arnold has worked many years for Giant Food and Drug Company.

The following are new pharmacies:

Kenilworth Pharmacy 6510 Kenilworth Avenue Riverdale, MD 20737

McAlpine Pharmacy 9141 Baltimore National Pike Ellicott City, MD 21043

The following pharmacy had a change of ownership:

Peoples Drug Store #1835 Francis Scott Key Mall Frederick, MD 21701 (Formerly: Rea and Derick)

The following pharmacy had a change of name:

Medicine Shoppe 325 S. Marlyn Avenue Baltimore, MD 21221 (Formerly: Eastern Pharmacy)

PHARMACY CHANGES—AUGUST 1985

The following are new pharmacies in Maryland:

Safeway Pharmacy #122 13069 Wisteria Drive Germantown, MD 20874

Safeway Pharmacy #868 14100 Baltimore Avenue Laurel, MD 20707

The following is a change of ownership:

Peoples Drug Store #1841 303 Long Meadow Road and Route 11 Hagerstown, MD 21740

The following store is now closed:

Super Super Pharmacy 8508 Liberty Road Randallstown, MD 21133

RECENT PHARMACY RELATED DEATHS

Oscar Samuelson, P.D., age 81, died August 8, 1985. Graduated from University of Maryland School of Pharmacy 1922. Practiced pharmacy until 1930 when he obtained a law degree from same school. Later became owner of the Tommy Tucker Variety Store Chain in Baltimore.

Deepest regrets to Stanley (Skip) Karmiol, University of Maryland School of Pharmacy 1955 on the passing of his sister Helen Zaben, on July 31, 1985.

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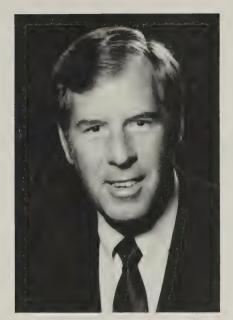
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The Drug House, an Alco Health Services Company announces the appointment of Garry P. McNamara to the position of Vice President of the Baltimore/Calvert Division of The Drug House.



The Drug House also announces the appointment of Richard L. Carter to Vice President/Sales and Marketing for the Company.



Commemorating the installation of the 1,000th QS/1 Pharmacy System at Bland's Drugs in Clarksburg, West Virginia are: (left to right) SDP President Glenn Hammett; store owners Ed Toompas, Bud Stanley, and Don Hutson; and QS/1 Marketing Director, Ken Couch.



Who are these guys? Music in Pharmacy may never be the same!

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PROPRANOLOL HCI CONTRAINDICATIONS

Propranolol HCI is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARN-INGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol HCI

WARNINGS:

CARDIAC FAILURE Sympathetic stimulation may be a vital component supporting circulator, the tion in patients with congestive heart failure, and its inhibition by beta blockade may been at all more severe tance. Although beta blockers should be avoided in overt congestive heart failure, and its inhibition by beta blockade may been at all more severe tance. Although beta blockers should be avoided in overt congestive to the used with close follow-up in patients with a history of tance who are well-compensated and are receiving digitalis and diuretics. Beta-adrener-gic blocking in arms at a 60 at reach the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers, can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranoid HCI should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exact phation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of a factors. IHCI therapy, Therefore, when discontinuance of propranolol HCI is planned, the factor is a particular produced over at least a few weeks and the particular should be cautioned against interruption or cessation of therapy without the play scients advice. If propranolol HCI therapy is interrupted and exacerbation of an interruption or cessation of the propranolol HCI therapy is interrupted and exacerbation of an interruption or constitution of the propranolol HCI therapy is interrupted and exacerbation of an interruption of constitution of the propranolol HCI therapy is interrupted and exacerbation of an interruption of the propranolol HCI therapy is interrupted and exacerbation of an interruption of the propranolol HCI therapy is interrupted and exacerbation of an interruption of the propranolol interruption of the propranologic propranolol interruption of the propranologic propran NONALLERGIC BRONCHOSPASM (e.g., chronic bronchitis, emphysema)—PATIENTS V BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS Propranolol HCl should be administered with caution since it may block bronchodilation pr duced by endogenous and exogenous catecholamine stimulation of beta receptors

MAJOR SURGERY: The necessity or desirability of withdrawal of beta blocking therait is proto major surgery is confroversial. It should be noted, however, that the impaired about, of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesther as a surgical procedures

Propranolol HCI, like other beta blockers, is a competitive infinition of beta Propraidon Not, like this beta blockers, a mount is effects can be reversed by administrational such against e.g. dobutamine of proterenol. However, such patients may be subject to protracte J severe hypotens, while the culty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABLES AND HYPOGLYCLMIA Beld adrenends brocks femal, present the appearance of certain premonitory signs and symptoms to after and pressure charges to a few hypograms are above 15 or dependent diabetes. In these patients, it may be more 11th to adjust the 15 age of insulin.

IHTROTOXICOSIS Beta blockade may mask certain care a sign of hyperthyroidistr. Therefore about withdrawal of propranolol may be followed by an exacertar or of sun tomosthyperthyroidistr. Including thyroidistorm. Propranolol does not distort thyroid are

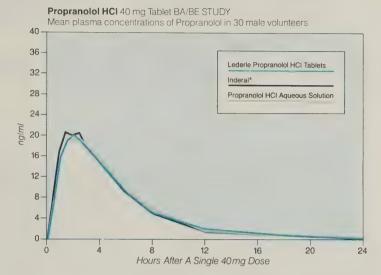
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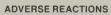
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Cardiovascular Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Lightheadedness; mental depression manifested by insomnia, lassitude, weakness, faltique, reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics

Gastrointestinal Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress

Respiratory, Bronchospasm

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura Auto-Immune. In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucoculaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranoiol

sta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should a told that propranolol HCI may interfere with the glaucoma screening test. Withdrawal may ad to a return of increased intraocular pressure.

linical Laboratory Tests. Elevated blood urea levels in patients with severe heart disease, evated serum transaminase, alkaline phosphatase, lactate dehydrogenase

RUG INTERACTIONS: Patients receiving catecholamine-depleting drugs, such as reserne, should be closely observed if propranolol HCI is administered. The added catecholnine-blocking action may produce an excessive reduction of resting sympathetic nervous trivity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or thostatic hypotension.

arcinogenesis. Mutagenesis, Impairment of Fertility: Long-term studies in animals have en conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in bit rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of signifiant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dos selevels. Reproductive studies in animals did not show any impairment of fertility that was tributable to the drug.

egnancy. Pregnancy Category C. Propranolol HCl has been shown to be embryotoxic in timal studies at doses about 10 times greater than the maximum recommended human. Lise

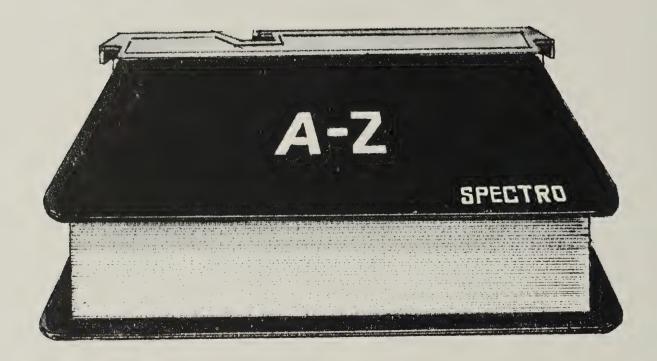
tere are no adequate and well-controlled studies in pregnant women. Propranolol HCl build be used during pregnancy and well-controlled studies in pregnant women. Proprantification of the should be used during pregnancy only if the potential benefit justifies the potential of the fetus.

ursing Mothers: Propranolol HCl is excreted in human milk. Caution should be exercised ten propranolol HCl is administered to a nursing woman.

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December, 1985 VOL. 61 NO. 12



OTC Eye Products

— Thomas Gossel – J. Richard Wuest

The Pharmacist and Hospice Care

— Bruce H. Krug

— Peter P. Lamy

Hospital Pharmacy Operations Survey Results Handling Questions About Drug Abuse

— Tony Tommasello

MID YEAR MEETING

Sunday, February 2, 1986
Annapolis Hilton Hotel
"1986 New Drug Update" — Gossel and Wuest
"What's Right With Pharmacy" — Jack Robbins
House of Delegates — Wine and Cheese Receptions

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Nathan Zilber practiced pharmacy in Maryland for more than 50 years. He owned a couple of drug stores, worked for others, and towards the end of his career worked as an information resource specialist for the A.A.R.P. pharmacy program. What made Doc Zilber a very special pharmacist was not where he worked, nor for whom, nor how much money he did or did not make, but how he practiced pharmacy. Because Doc Zilber was a professional. Because he stayed right on top of the latest information. Because he could apply that information to his practice setting. Because he cared about the patient. Because he cared about the students of pharmacy. Because he cared about our profession.

Two weeks before he died, he and Mrs. Zilber joined several seniors to participate in a panel discussion for first year pharmacy students at the School on issues of aging. He said there were some advantages. "People hold the door opened for you!" He admonished us to get out and talk to our patients, particularly watch out for the older patients. Communicate! One student asked how long a pharmacist could expect to practice the profession. Doc said, "Just as long as your legs can hold you up." Doc, I disagree. You practiced pharmacy sitting down, even as you spoke to our students that day. As the patient's advocate. Doc Zilber worked closely with the Elder-Ed program, with its faculty, students and with the elderly in the community.

He contributed to Maryland Pharmacy almost until the day he died, and we have suffered a loss. I did personally. Because Doc Zilber was my mentor and my friend.

Madeline Feinberg
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STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. II, NO. 11

Advising Consumers on OTC Eye Products. Part I: The Eye And Its Disorders

by J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

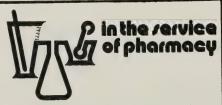
and

Thomas A. Gossel, R.Ph., Ph.D. Professor of Pharmacology and Toxicology Ohio Northern University Ada, OH

Goals

The goals of this lesson are to:

- discuss the physiology and function of the eye;
- 2. explain how to treat self-treatable eye disorders.



This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

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Objectives

At the completion of this lesson, the successful participant will be able to:

- 1. identify the different parts of the eye and their functions;
- 2. choose the appropriate OTC agents to self-treat eye disorders;
- 3. refer the patient to a physician when appropriate.

Consumers frequently seek the advice of pharmacists to relieve discomfort and treat diseases of the eye. The eye is a delicate instrument and even minor symptoms may signal the beginning of more serious problems. The pharmacist must, therefore, take care in his professional decision to refer the patient to an ophthalmologist or suggest self-treatment.

The first segment of this series of lessons on OTC eye preparations will review the function of the eye and the few conditions considered to be self-treatable.

Physiology And Function Of The Human Eye

The eye is comprised of a large number of specialized cells and tissues (Figure 1), each of which serves a specific function. Beginning from the outside and working inward, the cornea is the clear, transparent, lipid portion of the outer coating of the eveball which forms the anterior wall of the aqueous chamber. It is comprised of five layers of tissue, the outermost (epithelium) and innermost (endothelium) of which are lipophilic. This means that the cells of these two tissues repel water. The mid sections of the cornea are hydrophilic and contain water. The lipophilic nature of the cornea is an important feature in relation to the absorption of eye drops and the wearing of contact lenses. This will be discussed in more detail later.

The cornea is the initial tissue through which light rays must pass to reach the retina. There must not be any opacities or interference such as deflection or reflection. Therefore, corneal cells are clear and transparent. The cornea is kept shiny and lubricated by the tear fluids which moisten its surface and fill in any irregularities in the epithelium which can rapidly regenerate itself. Unless it is diseased, the corneal epithelium has the capacity of covering abrasions within 24 hours. Unlike most other tissues, a healthy cornea will heal without leaving a scar.

There are no blood vessels in the cornea, but there is a high number of nerve fibers which make it one of the body's most sensitive organs. Since the cornea is transparent, one sees the iris and its center black opening, the pupil. The cornea is circular and fits like a watchglass into the double

edge of the sclera.

The sclera is the white part of the eye that forms a relatively tough covering. Along with the cornea, it constitutes the external protective covering of the eye. The sclera, which makes up the greatest portion of the external eye, is covered by a filmy moist membrane called the conjunctiva. It extends from the junction of the cornea and the sclera outward to the margins of the eyelid.

The conjunctiva is a thin transparent layer of mucous membrane which lines the posterior portion of the eyelids and the anterior portion of the sclera. It is responsible for supplying blood, nutrition and oxygen to the corneal tissues, and for removing waste products. The conjunctive plays a major role in maintaining the health of the cornea.

The anterior chamber is the space bounded in the front by the corner and behind by the iris. It is filled with aqueous humor, a clear, watery fluid which fills the anterior chamber within the frontal part of the eye

The **iris** is a colored, circula membrane suspended behind the cornea, immediately in front of the lens. The iris is connected to the cili

ary body and separates the anterior and posterior chambers of the eye. The black hole in the center of the iris is the **pupil** which reflexly controls the amount of light admitted to the retina. The iris and pupil act as a shutter. In bright light, the pupil constricts. In dim light, the pupil dilates.

The color of the iris depends on the amount of melanin it contains. If only a small amount is present, the reflection from the pigment on the posterior layer is scattered and the iris appears blue. With a moderate amount, the iris will be hazel, and with a large amount of melanin the iris will appear brown. The **crystalline lens** is a transparent, colorless, biconvex structure which is suspended from the ciliary body. It lies between the aqueous and vitreous humors and functions to focus the rays of light coming through it onto the retina. The crystalline lens has no direct blood supply. It is nourished by the aqueous humor.

The **ciliary body** is a thin muscle which is responsible for accommodation. It performs this function by controlling constriction and dilation of the iris and the refractory power of the crystalline lens. The ciliary body also secretes aqueous humor.

The posterior chamber of the eye

forms the space between the back of the iris and the front of the crystalline lens. Like the anterior chamber, it is filled with aqueous humor.

Two other important types of tissue in the anterior eye are the trabecular meshwork and Canal of Schlemm. The **trabecular meshwork** is a porous-like structure surrounding the entire circumference of the anterior chamber. Aqueous humor flows through it into the Canal of Schlemm.

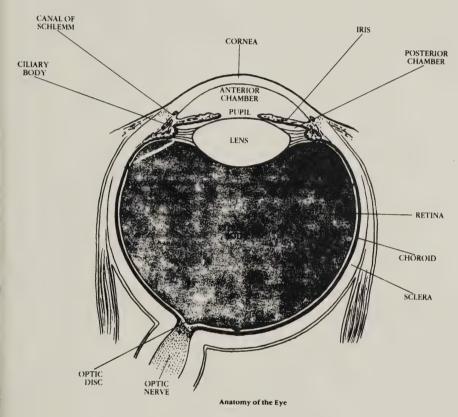
The Canal of Schlemm is an ovalshaped channel that also surrounds the anterior chamber outside the trabecular meshwork. It is situated at the juncture of the sclera and the cornea. It is through this canal that aqueous humor is excreted after it has circulated between the lens and the iris, and between the iris and the cornea. The Canal of Schlemm is connected with the venous blood supply.

The area immediately behind the crystalline lens is filled with vitreous humor. This is a transparent, colorless mass of soft gelatinous material that fills in the eyeball and holds the lens and retina in place. Functionally, the vitreous humor is inactive. It can be likened to the space between the lens and the film in a camera. Sometimes small particles form within the vitreous humor and show up in the field of sight as opacities, more commonly called "spots."

In the posterior portions of the eye, two of the major tissues are the choroid and retina. The **choroid** is the vascular bed which provides the blood supply to the retina. The **retina** is the innermost coating of the eye. It contains the light-sensitive nerve elements. It is comprised of two distinct types of cells called rods and cones.

Visual acuity and color discrimination are functions of the cones, while the rods are responsible for determining motion and vision at low degrees of illumination. If the cones do not function, the individual is color blind. If the rods do not function, the resulting condition is night blindness.

Depth perception and accommodation result from each eye seeing an object at a slightly different angle. Through the **optic nerve**, the brain fuses slightly dissimilar images. The combination of these angular views



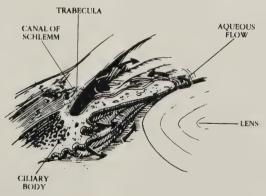


FIGURE 1.

provides depth perception. Accommodation is the adjustment of the eye for seeing objects at different distances, and is accomplished by changing the shape of the crystalline lens through the action of the ciliary muscle, thus focusing a clear image on the retina. The stimulus for accommodation is a blurred vision on the retina. For example, when an object moves toward a person, the ciliary muscle contracts. This in turn changes the shape of the lens, therefore increasing its refractory power. When objects move away, the opposite action occurs.

Color vision is made possible because the cone cells in the retina contain three photosensitive pigments in their outer portions. As they adsorb light rays of various wavelengths, i.e., red, yellow and blue (the primary colors), the pigments mix together to form all of the colors of the spectrum and pass these impulses on to the optic nerve through chemical reactions.

Errors in Accommodation

Although the following conditions will be discussed in much more detail in a future lesson on contact lenses, they will be defined here.

Astigmatism is a condition in which the cornea is not perfectly spherical. Because of this, there is a refractive error which prevents light rays from converging to a single focus on the retina.

Hyperopia, more commonly called far-sightedness, is a refractive error in which the focus for the rays of light coming from a distant object occurs at a point behind the retina. This causes blurred vision.

The opposite of this condition is myopia, or near-sightedness. In this instance, a refractive error causes the point of focus for rays of light coming from distant objects to be in front of the retina. Vision is blurred for distant objects.

All three of these conditions can be easily corrected by placing an artificial lens, i.e., spectacles or contacts, between the object and the cornea.

Presbyopia is a gradual lesssening of the power of accommodation due to the physiological changes of aging. It becomes more noticeable after age 40 by virtue of blurred near-vision. As people age, the contractile

ability of the ciliary muscles decreases and accommodation of closeup objects suffers.

Photophobia is an abnormal sensitivity to and discomfort from light. At times, it can become so severe that the affected individual is afraid to enter brightly lit areas.

A cataract occurs when the crystalline lens of the eye, which is normally transparent, becomes opaque due to the precipitation of foreign substances, or direct damage as a result of disease or trauma. The removal of the cataract is referred to as aphakia which basically refers to the absence of the lens of the eye.

Self-Treatable Eye Disorders

There are very few disorders of the eye that can be correctly selfdiagnosed and/or self-treated (Table 1). Except for tear insufficiency and minor irritation, the eye preparations available without a prescription merely provide symptomatic relief.

TABLE 1 Self-Treatable and Non-Self-Treatable Ocular Conditions*

Self-Treatable	Corneal edema** Minor inflammation Minor irritation Tear deficiency
Non-Self-Treatable	Corneal ulcers Embedded foreign bodies Flash burns Glaucoma Infections

^{*}As determined by the FDA Advisory Panel on OTC Ophthalmological Drugs

Problems arise when persons misdiagnose their conditions. Usually they find a product, via trial and error, that relieves their condition. The condition may worsen, or it may prevent early definitive physicianinitiated therapy with the correct drug. For this reason, it is best to stop using the OTC product and contact a physician if the condition does not respond within a few days.

There are three ocular conditions that are generally considered to be self-treatable: tear deficiency, corneal edema and minor inflammation and irritation.

Tear deficiency results from inadequate production of lacrimal and ocular secretions. Since the epithelial layer of the cornea is hydrophobic, it repels water. However, the corneal tissues require water and its absence

for just a few moments can lead to the onset of corneal deterioration.

Tear film is made up of three layers of substances, the components of which are listed in Table 2. The innermost layer of **mucin** is deposited by the conjunctiva as the eyelid blinks. Mucin adheres to the corneal surface, lowers its surface tension, and converts it from a totally hydrophobic to a relatively hydrophilic mode so that the lacrimal secretion, which is basically normal saline, can spread over the cornea.

TABLE 2 Components of Tear Film

nicals

drates

lucin Layer	Glycoproteins — chen composed of carbohyc and proteins
queous Layer	Albumin Amino acids Bicarbonate Chloride Glucose Lysosomes Phosphate Potassium Sodium Urea
	Water

M

Lipid Layer

Fatty alcohols Lecithin Non-polar lipids Phospholipids Triglycerides

The lacrimal secretion, i.e., the aqueous layer of tear film, contains the key components for corneal nutrition and metabolism as well as antimicrobial lysosomes. These are substances that lyse or destroy microbial cells.

The outermost layer of tear film lipid layer, is also supplied by the conjunctiva. It provides stability to the lacrimal secretion, prevents rapid evaporation, holds it there for awhile, and spreads it over the cornea.

Dry eye syndrome resulting from tear deficiency can be extremely painful when non-wetted areas of the cornea are continually exposed to atmospheric irritation and me chanical irritation from blinking Artificial tear products are intended to adsorb onto the cornea, increasiviscosity, and provide pain relief. Periodic moist compresses are also helpful as is raising the humidity of environmental air. Severe cases materials are corneal bandage type of contact lens.

The ocular demulcents and emol

^{**}After diagnosis by a physician

lients are useful in alleviating the burning discomfort and dry feeling associated with tear deficiency. While there are causes of tear deficiency that need supervision, its treatment usually involves long-term use of ocular lubricants. Except for special drug delivery systems such as the LacrisertTM, there are no prescription-only tear deficiency products that are clearly more effective than the OTC demulcents and emollients.

Corneal edema cannot be selfdiagnosed. It is a condition that involves excessive water inside the epithelial and endothelial layers of the cornea. This leads to swelling of the corneal tissues and impaired vision. Symptoms include foggy vision and/ or haloes around light, irritation, photophobia and excruciating pain. The condition can result from a number of underlying causes such as glaucoma, degeneration of corneal cells, inflammation of the iris, other ocular inflammations, infection, and excessive wearing of contact lenses. In each instance, the cause must be corrected. Hypertonic agents, e.g., 5% sodium chloride, are recommended for temporary relief of corneal edema, and can be purchased without a prescription. However, a physician must first diagnose the condition and institute corrective therapy.

Minor irritation and inflammation of the eye are most often exhibited by burning, itching, smarting, tearing and redness. These symptoms can be alleviated with a simple eyewash, astringent, demulcent, emollient or vasoconstrictor. The types of ocular inflammation and irritation which are amenable to selfmedication with OTC eye preparations are those caused by the presence of loose, easily removed foreign particles, air borne pollutants such as cigarette smoke and allergens, and chlorinated water in swimming pools.

Foreign bodies should be removed by a professional to prevent damage of delicate eye parts. The following conditions are also not appropriate or self-medication: uveitis, which is inflammation of the choroid, ciliary body or iris; kerititis, which is inflammation of the cornea; and cornell ulcers, which can cause blindness from the treated properly. Glaucomand flash burns are also not self-

treatable.

Flash burns are also called "welder's eye" and result from ultraviolet radiation burns from welding equipment when the eyes are not properly protected. Minor flash burns are self-limiting but not self-treatable. They often heal if the eye is rested under an eye patch. When treatment is initiated, it generally involves topical antibiotics, cycloplegics, and systemic analgesics.

Styes, Pink Eye And Crusty Eyelids

These conditions are in the "twilight zone" of therapy since there are no proven, effective anti-infective agents safe for OTC use. The best advice is to suggest that the individual see a doctor. However, we know that this advice will often not be followed, so the next section is offered to assist the pharmacist in making good professional judgement.

A stye (hordeoleum) results from an infection with pathogenic staphylococci in sebaceous or sweat glands, or from an eyelash follicle in the margin of the evelid (bleph). This is exhibited by localized tenderness, redness, swelling, and possibly, pus formation. When pus is present, the infective organisms are invariably staphylococci. The condition can be treated with warm water or saline compresses to "draw" the accumulated pustular material and bacterial colony to the surface. When this comes to a head, the pustule (pimple) can be carefully lanced and expressed. Premature squeezing or pressing of the pustule can lead to spread of infection into the subdermal or adjoining areas. The effective anti-infective agents, such as bacitracin or the sulfonamides, are considered to be unsafe for over-thecounter use. Minor conditions are self-limiting and much of the irritation can be alleviated by applying an OTC demulcent or emollient such as petrolatum/yellow wax to be discussed in the next lesson of this series on OTC eye preparations.

The crusty material that accumulates on the eyelids due to inflammation (blepharitis) results from exudation from overactive sebaceous glands, bacterial by-products, or both. These causes can be differentiated since the seborrheic crusts are usually oily while the staph-induced

type produces dry scales and small ulcerations in the surrounding tissues.

Treatment of staphylococciinduced blepharitis involves moist
compresses to soften and remove the
scales, and the application of an appropriate antibiotic, none of which
are available OTC. The seborrheic
form of blepharitis requires correction of the underlying scalp problem
that is adding to the excess sebum in
the area. This is generally accomplished by good hygiene and the use
of OTC anti-seborrheic shampoos.

Pink eye is actually conjunctivitis due to infection by bacteria, fungi or viruses, or to an allergic reaction. It is commonly called pink eye because of the redness of the sclera along with exudation and a feeling of sand in the eye. Proper treatment requires identification of the causative organisms and use of an appropriate antiinfective agent. The milder forms are self-limiting and will clear in a few days with or without treatment. The more serious cases require proper treatment to avoid secondary corneal infections, corneal destruction or blindness. In milder cases, OTC eye demulcents, emollients, astringents and vasoconstrictors are generally helpful. These will be discussed in more detail in the next lesson in this series. The importance of contacting a physician if any eye condition does not clear within a few days of selftreatment will be stressed again.

A common cause of eye irritation resulting in the aforementioned conditions is cosmetic agents. Mascara and other eye make-up product applicators often become contaminated with microorganisms. Women with signs and symptoms of blepharitis or conjunctivitis, especially if recurrent, should be warned that the cause may be their eye cosmetics. Mascara should certainly not be used to hide blepharitis because it may further aggravate and prolong the condition. It may be helpful to replace mascara applicators frequently. Continual use of ocular vasoconstrictors is merely a cover-up of the underlying cause.

Ecchymosis is a "black eye." It is best treated by applying an icepack.





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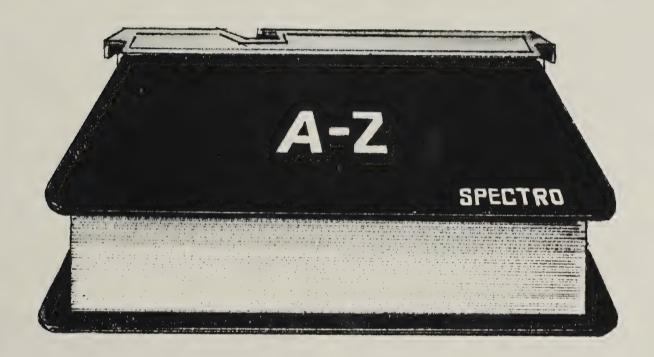
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THIS AND THAT ABOUT PHARMACY

by Leon Weiner, P.D.

Spotlight on Milton Proudfoot, P.D.

Oakland in Garrett County is a great place to visit in spring, summer and early fall, but not in the winter! Downtown Oakland has three pharmacies within walking distance. They are Englander's Pharmacy, Gregg's Pharmacy and Proudfoot's Oakland Pharmacy.

Our subject this month, Milton H. Proudfoot graduated from a military academy in southern Maryland and then went on to graduate from the University of Maryland Pharmacy School in 1975. Today continuing education keeps him abreast of changes that occur in pharmacy.

After graduating from Pharmacy School, Milt worked for a chain store for two years prior to joining his father's business at Proudfoot's Oakland Pharmacy in Oakland. He had worked there from age 12 as a stock boy and cashier. In addition to the retail business, it services a local nursing home.

Dr. Milton finds plenty to do in the mountainous Garrett County. He spends his winters scrimshawing powder horns, making leather goods and building custom muzzle loading guns all of which are in an 18th century style. To complete an outfit of this period, Milt takes up needle and thread to make clothing from original patterns.

When spring comes and the Garrett County snows are gone, he is off to rendevous with the mountain men. His skills of shooting and knife and tomahawk throwing have won him many trophies at these meets. History classes from elementary school to college have welcomed his presence as an image of days gone by.

The warm winds of spring and summer also signal home building time and that is when Milt helps in constructing log homes. He told me he wants to design and build one of these someday by himself. Dr. Milt states that this job keeps him out of the ivory tower that many professional people get into—"believing that everything we do is right just because it's us that's doing it. I see a lot of people with a "God" complex . . . they seem to forget the person across the counter is not just another insurance claim."

In the autumn, he takes to the hills for his favorite sport—hunting squirrels, rabbits, grouse, and deer. His freezer is stacked with home butchered meat by the season's end. His home recipes complete the cycle of skilled accomplishments.

All through the year, you may find him painting,

sketching or photographing the animals, people and scenery of Garrett County.

And you know—he says it's all just for fun.

Milton H. Proudfoot is the son of pharmacist Robert Proudfoot, who has owned Proudfoot's Oakland Pharmacy for quite a number of years. Robert graduated from West Virginia University in 1950.

LOVE & MARRIAGE

Mr. Marvin L. Venick, UofMD Pharmacy 1955 and wife announce the engagement of their daughter, Barbara Ellen to Ralf Wilhelm of Scottsdale, Arizona. Dr. Venick is presently employed as a pharmacist at Giant Food and Drug Company.

Mr. Donald Dagold, UofMD Pharmacy 1955 and wife announce the engagement of their daughter, Cindi Robin to Michael Steven Pollack of Potomac, Maryland. Dr. Dagold is the pharmacist-owner of Watermont Pharmacy, Inc., in Ellicott City, Maryland.

Mr. Albert Lichtman, UofMD Pharmacy 1956 and wife announce the marriage of their daughter, Stephanie Jolene to David Mark Citron of Rosly Heights, New York. Dr. Lichtman is the pharmacist-owner of Holabird Pharmacy, Inc. in Baltimore.

Mr. and Mrs. Charles E. Shores of Lutherville, announce the engagement of their daughter, Michele Louise to Michael Paul Sawicki. Michele is a 1985 graduate of the UofMD Pharmacy School.

Mr. Harold Sherr, UofMD Pharmacy 1954 and wife announce the engagement of their daughter, Marcia Gail to Alan Curtis Simkin. Dr. Sherr is now employed as a pharmacist for Giant Food and Drug Company.

Mr. Robert B. Stiekman, UofMD Pharmacy 1961 and wife announce the engagement of their daughter, Margery Sue to Neil Allan Klotzman. The wedding is to take place in July 1986. Dr. Stiekman is presently employed as pharmacist for Rite Aid Drug Company.

Hedy Cylus, UofMD Pharmacy 1973 was married to Stanley Gleiman on October 13, 1985. Dr. Cylus has worked for Giant Food and Drug Company and is now employed at Eastpoint Medical Center.

Arthur Schwartz, UofMD Pharmacy 1979 recently married Karen Horowitz of Baltimore. Artie holds an M.B.A. from Loyola College, M.S. from the University of Baltimore and is currently a Ph.D. candidate at the UofMD School of Pharmacy. His wife is the

granddaughter of the late A. Milio Sachs, P.D., who was one of the owners of Sachs Brothers Pharmacy on Reisterstown Road, Baltimore. Dr. Sachs was a 1929 graduate of the UofMD Pharmacy School.

PHARMACY CHANGES—SEPT. 1985

The following pharmacies are now closed:

Revco Drug Center #1054 1969 E. Joppa Road Baltimore, Maryland 21234

Prescription Plus Pharmacy 9105-M All Saints Road Laurel, Maryland 20707

The following is a new pharmacy:

Weis Pharmacy #122 9270 All Saints Road Laurel, Maryland 20707

The following has new name and ownership:

Govans Professional Pharmacy 5010 York Road Baltimore, Maryland 21212 (Replaces York Professional Pharmacy)

The following has new location:

Fallston Pharmacy 2112 Belair Road Fallston, Maryland 21047



ALEXANDER J. OGRINZ, P.D.

The above photo, taken during the holiday season of 1970, shows Alexander J. Ogrinz and one of his closest friends, the late Francis S. Balassone, along with other members of the Division of Drug Control, from left to right are John O'Hara, Paul Perzynski, Charles Tregoe, Frank Balassone, Leon Weiner, Al Ogrinz and Jerry Wittik.

The Maryland Pharmacy community lost a very active member on September 16, 1985 when Alexander J. Ogrinz, Jr. passed away. A graduate of the UofMD Pharmacy School in 1934, he worked for 10 years at the Johns Hopkins Hospital, becoming chief of its pharmacy department. He then became part owner of the Burris and Kemp Pharmacy and Homeland Pharmacy, both in Baltimore City. In 1970 he retired from the pharmacy profession and then proceeded to work for the State Department of Health until 1979.

During his professional career, Al was president of the Baltimore Metropolitan Pharmaceutical Association in 1958, president of the Maryland Pharmaceutical Association in 1965 and president of the Alumni Association School of Pharmacy UofMD in 1953–1954. In 1967, he received the Alumni Association School of Pharmacy Honored Alumnis Award. Dr. Ogrinz was also a former president of the State Board of Pharmacy on which he served from 1955 to 1970. Al was the president of the Lan Lea Corporation which operated an apartment motel, The Valley Pharmacy and other ventures in Timonium.

Dr. Ogrinz is survived by his wife, the former Camilla Vondracek, a son, Alexander J. Ogrinz III, a daughter, Cordelia E. Ogrinz and 2 grandsons.

It was my pleasure to work with Al for a number of years. First, I helped him and the members of the Board of Pharmacy in monitoring the pharmacy examinations. Later on, when Al became a member of the Division of Drug Control, we were united again. Al was a born leader, sincere, kind, and extremely intelligent in various subjects. In talking with him, you knew he would always come through with a good response. He also had a great sense of humor. Al loved to hear a joke and was not bashful in telling one. I often think of him and the way he would change from a serious expression to a smiling face with a great hardy laugh.

RELATED PHARMACY DEATHS

Leo Charles Rettaliata, UofMD Pharmacy 1918, passed away October 12, 1985. Former owner of Rettaliata Pharmacy on Charles Street in Baltimore City. Also, former President and long time member of the Baltimore Veteran Druggists Association and long time member of the Wedgwood Club.

Deepest regrets to Harry McKenny, UofMD Pharmacy 1958 and wife on the passing of their son, Harry David McKenny, on September 16, 1985. Dr. Mc-Kenny is now working for Giant Food and Drug company after many years with Read's Drug Company.

Deepest regrets to Herbert C. Wagner, UofMD Pharmacy 1962 on the passing of his wife, Ruth, on September 14, 1985. Dr. Wagner is the former owner of Wagner's Drug Store on Cold Spring Lane in Baltimore.

PHARMACY NEWS IN BRIEF

Bob Snyder, UofMD Pharmacy 1955 is now associated with Magill Yerman and Company, Realtors. He is a former member of the Maryland State Board of Pharmacy.

Ellis Levi, UofMD Pharmacy 1959 went on to Dental School and now practices dental implantology at his offices in Lutherville and Dundalk. Dr. Levi is now available to speak on topics such as "Dentures vs. Implants: The Future of Modern Dentistry, "Medical Insurance and Dental Care: What Will It Really Cost?" and "Dental Care and the Elderly." For information or to schedule a program, call Casey Weiner at 486-2512 (I wonder if Ellis would also speak on his exciting days at Pharmacy School)

Lance Berkowitz, G. W. University 1965, past president of the Reisterstown-Owings Mill Lodge of B'nai B'rith was named outstanding lodge president in District Five from among the 255 lodges in a 7 state area, representing over 30,000 members at the just completed 1985 District 5 Convention of B'nai B'rith International, held in Hollywood, Florida. He was chosen for his outstanding leadership in directing the activities of the group.

Dr. Berkowitz, 42, a registered pharmacist is associated with the Arcade Pharmacy in Northeast Baltimore. He is married to the former Fran Bernstein and has 2 children, Robyn and Richard.

Pharmacist Nan McCurdy-Mitchell, St. Louis University 1983, and her husband, Phil, were very impressed by their visit to Nicaragua. Because of this, they sold all of their possessions out of their East Baltimore home in order to raise enough cash to finance their trip and stay in that country for approximately a year. They want the people from Nicaragua to meet American people and hope much good will come from it.

"Internally Speaking" which is the monthly news letter of Baltimore County General Hospital reports much progress has been made in the operation of the BCGH Pharmacy located at 5401 Old Court Road, Randallstown. Much of this is due to the effects of Louise Leach, UofMD Pharmacy 1974 and her excellent staff of pharmacists and technicians.



LETTERS



Dear Mr. Banta:

Within the past three months, I have been contacted by physicians from all parts of the country as well as patients with diabetes, nurse educators, and diabetes associations concerning the subject of substituting one brand of insulin for another. The purpose of this letter is to request that you publish in your newsletter or journal (that you send to the pharmacists in your state) some information about the differences in the various brands of insulin and the potential problems that switching insulins can cause.

Every pharmacists should read the federal FDA's approved package insert "WARNING" for insulins. It states in part, "Any change of insulin should be made cautiously and only under medical supervision. Changes in refinement, purity, strength, brand (manufacturer), type (regular, Lente, NPH, etc.), species (beef, pork, human), and/or method of manufacturer (recombinant DNA human insulin versus animal-source human insulin) may result in the need for a change of dosage." In addition, the amount of excess zinc, protamine and the type of preservative can differ from one brand to another. In one study done by Dr. John Galloway, 81% of patients changing from one type of insulin to another required an adjustment in dose.

Patients exposed to different insulins may experience varying degrees of difficulty in maintaining consistent glycemic control. The many differences in the insulins may result in an increase or a decrease in the incidence of local or systemic allergy, serum insulin concentration, serum antibody concentration, insulin requirement and body weight.

The pharmacist's role in the care of the patient with diabetes is significant and is well recognized by patients and health care personnel. The pharmacist should make a special effort to see to it that changes in insulin therapy be made under medical supervision and that the patient is trained to self monitor blood glucose to insure that the insulin dosing regimen is normalizing blood glucose levels. Pharmacists should not change a patient's insulin without having the patient consult their physician in reference to the implications and possible complications that might result. Some of the physicians who have called me have threatened law suits against pharmacists that substitute one brand for another. I appreciate your bringing this information to the attention of the pharmacists in your state.

Sincerely, R. Keith Campbell Professor of Clinical Pharmacy



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The Pharmacist and Hospice Care

by Bruce H. Krug, Pharm.D. and Peter P. Lamy, Ph.D.

Introduction

The term "hospice" is an old one, having originated during the crusades. It denoted a way station for sick or dying travelers to the holy land. Dame Cicely Saunders established the first "modern" hospice in London in 1967. In this country, the first hospices were introduced just a decade ago. The number of hospice programs has jumped from only one in 1975 to about 1,000 in 1982 (46% of which were hospital-owned) to over 1,345 today. In another 10 years, there could be as many as 6,800, according to estimates by the National Hospice Organization (NHO).

Research has shown that hospice care is substantially less expensive than is institutional care. In 1984, in the Journal of Risk and Insurance, a study was published which showed that the average cost for six months of hospice care in the home for a cancer patient was \$1,319, compared with \$8,559 in a municipal hospital. Nevertheless, financing is the biggest problem in the expansion of hospice programs. Medicare benefits average about \$53/day (just increased from \$46/day in October 1984), but actual costs are probably \$70/day. Increased Medicare benefits, it is feared in some quarters, may add as many as 100,000 patients to hospice care. Thus, while individual care is less expensive than institutionalized care, the aggregate cost of hospice care would certainly increase. Hospice Medicare benefits will be reviewed by Congress in 1986, and there is no assurance that they will be kept at current levels or increased.

The Unit of Care is the *Patient* and the *Family*. Work with the family is most important in terms of crisis intervention and preventive care. The need for family was substantiated by a study released last fall by the National Academy of Science. The study found that family members can be particularly vulnerable to physical and mental illness following the death of a family member. The goal of hospice patient care is to provide symptom control through appropriate palliative therapy. Symptom control includes the assessment of

and response to physical, emotional, social, and spiritual needs. In other words, once an incurably ill patient enters a hospice program, the focus of care shifts from treating the disease to easing a patient's physical and mental distress. Active treatments are rare. One might see occasional radiotherapy to ease a patient's swallowing difficulties, for example. Other active treatment, if suggested, should meet the most rigid standards regarding attendant morbidity, probability of response, and mean duration of response and must not be undertaken without close consultation with the family. Failure to recognize that active treatment is most often inappropriate can result in unnecessary problems and suffering.

The "palliative" nature of hospice care was recognized by the Victoria Hospital in Canada, which termed its hospice care program the Palliative Care Service, emulated by the palliative care service at the Philadelphia Fox Cancer Center.

TABLE I
The Hospice Care Team

Attorney Clergy Dietitian Nurse	Pharmacist Physician Social Worker
------------------------------------------	------------------------------------------

The Team and The Place of Care

Hospice care is offered by a multidisciplinary team (Table I). Hospice care, as currently practiced, can be offered in the home, nursing home, hospital, or other appropriate location. It is an exciting and sensible approach to the care of the terminally ill, for which the patient's own home is the most ideal setting. This setting does not deprive the patient of familiar surroundings and the close presence of the family. Ideally, a family member or close friend should be primarily responsible for the patient's care, supported as needed by team members. The major goal, then, is to meet the patient's wishes and desires.

The family and other caregivers can meet with the team initially so that the disease, prognosis, and needed care can be discussed in an honest, open, and caring manner. It is essential that patients and families be given accurate information so that they can know what to expect and can be prepared to deal with it. The team

Dr. Krug is Consultant and Director, Clinical Services, Howard and Morris Pharmacy and Assistant Clinical Professor, University of Maryland, School of Pharmacy, Baltimore, MD 21201

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, Chairman, Department of Pharmacy Practice and Administrative Science, University of Maryland School of Pharmacy, Baltimore, MD 21201.

can remain readily available for further support when needed. It is crucial that families and patients not be given false hopes as this will destroy the trust necessary for effective communication and team effectiveness. On the other hand, the approach does not need to be, nor should it be, utterly pessimistic. Those concerned should be made to understand that the patient can and will be made comfortable and allowed to obtain the most from the remaining days. The team can provide spiritual counselling so that the imminent demise of the patient can be understood and accepted. Positive intervention can help to allay the guilt feelings often felt by caregivers. An inpatient referral center should be made available for respite care to help reduce the immense burden on the family. This center can also serve as a place for the care of acute crises, such as hemorrhage, and if needed for the terminal event.

The Hospice Patient and The Patient's Problems

About 95% of hospice patients, who usually enter a program in the last six months of their life, are cancer patients, but there is an increasing number of patients with progressive neurological and pulmonary diseases. The patient faces and must overcome a host of physical and mental problems (Tables II and III). Foremost is pain and the fear of pain. But there is also depression (the fourth stage of dying as set forth by Dr. Kuebler-Ross) and fear, fear of multilation, isolation, loss of control and increasing dependence, fear for the future of loved ones, of the unknown and what has been termed "reflected" fear, i.e., the fear seen by the patient in the eyes of the family and friends.

At times, significant but temporary problems may appear and must be dealt with, such as malignant bowel obstruction for example.

The Pharmacist's Care Contribution

A careful and thorough medication history can serve as a starting point in the therapeutic process. Important aspects include allergies and sensitivities, ability to swallow, use of non-prescription medications, response to previous attempts at pain control, identification of duplications, and drug interactions.

The most important area in which the pharmacist can be helpful is in the assessment and control of pain. Much experience has been gained recently in the proper use of narcotic analgesics in the prevention of pain, be-

TABLE II
The Shifting Symptom Complex

TABLE III
Identified Problems in Patients with Advanced
Irreversible Disease

Percent Incidence	Problem
71	Weakness
49	Constipation
46	Depression/Loss of Contro
38	Anorexia
28	Nausea
24	Vomiting
21	Shortness of Breath
10	Painful Decubitis
6	Difficulty Swallowing
5	Dry or Sore Mouth

Data based on 100 home care patients at The Connecticut Hospice.

ginning in this country with the use of "Brompton" type mixtures in the mid-1970's. The term "Brompton's Mixture" is a generic one for opiate-cocaine mixtures similar to the one used at the Brompton Chest Hospital in England. A typical formulation contains a variable amount of morphine or heroin, 10 mg. of cocaine, 2.5 ml. of simple syrup, and a sufficient quantity of chloroform water to make a 20 ml. dose. However, a survey of more than ninety British teaching and general hospitals revealed almost as many different formulas. These varied in active constituents and the vehicle. Some contained morphine, some heroin, and some both. The alcohol content ranged from zero to 40%, and several contained a phenothiazine. For these reasons, direct comparisons between reported experiences are somewhat difficult. Sufficient published data exist, however, to make some general statements concerning the use of these mixtures. Most of the published data has come from England and Canada and many have come from the same group. Most studies have found the mixture to be effective in controlling pain in from 75-90% of patients, and, significantly, patients in hospice settings consistently had the highest frequency of response to the mixture. Reasons cited include the total comprehensive medical, surgical, and spiritual care given in these specialized units, and the fact that the mixture is more likely to be given regularly in these units rather than on an "as needed" basis likely in other settings. In all reports, at least 10% of patients have had little or no response to the mixture and needed additional medical, surgical, and psychological help.

The concept of pain prevention rather than treatment is frequently cited as an important factor in the use of analgesics in these studies. There is scientific support for this concept. Pain, particularly the pain of terminal illness, is greatly influenced by such factors as the knowledge of impending death, fear of disfigurement by the disease, worries about family or financial matters related to the prolonged illness, and the actual fear of anticipation of further pain. All of these factors may contribute to an intensification of the actual physical pain itself. By giving the analgesic regularly, every

four hours, pain is prevented rather than treated, and as the sensation of pain becomes a memory rather than a current experience, the vicious cycle of anticipation and amplification is broken. There is also, quite often, unfortunately a fear of addiction on the part of the physician, nurse, patient, and family. Most studies have shown, however, that tolerance does not develop to the analgesic and, in fact, when given regularly to prevent pain, many patients need less medication to control their pain over time. Although tolerance to narcotics is a well documented pharmacologic phenomenon, in clinical use the actual experience of pain and the subsequent craving for relief has been blamed for much of the need for escalating doses. It is the use of the "as needed" order that is often responsible for rapidly escalating dose requirements. In terminal cancer patients, physical addiction to narcotics is of no concern, but the fear of addiction can easily lead to tragic undertreatment of these unfortunate patients.

The introduction of Bromptom's Mixture has served a very important purpose in that it has made us aware that proper dosing of oral opiate analgesics can achieve pain prevention as opposed to treatment as was typical previously with the widespread use of "as needed" orders. It has become apparent, however, that what was important about Bromptom's mixture was not the ingredients but the way and the setting in which it was used. Two recent studies have shed some light on the value of cocaine in the mixture. In the first, mixtures with and without cocaine were compared. It was found that the addition of cocaine resulted in a small but statistically significant increase in alertness. Stopping the cocaine had no demonstrable effect, probably because cocaine was of borderline effectiveness and that tolerance to it occurred in a few days. Patients can become restless, agitated, and confused, and can present with hallucinations when given cocaine. Symptoms abate only with its withdrawal. A similar trial compared a traditional morphine-cocaine mixture with plain morphine. Pain and side effects were assessed. The addition or withdrawal of cocaine or alcohol made no difference in pain, nausea, drowsiness or confusion. As a result of these studies, both hospice centers and many others have abandoned the routine use of cocaine, and now use it, or dextroamphetamine, only for patients with persistent, troublesome drowsiness while on morphine.

Many patients need an antiemetic in the first few weeks of therapy to counteract the opiate-induced nausea. Prochlorperazine is the preferred agent since chlorpromazine increases the sedative effects of morphine considerably. It is best reserved for the very anxious patient. Despite statements from many sources to the contrary, there is no convincing evidence that phenothiazines can potentiate the analgesia of narcotics. A recent review of the literature found important design and reporting defects in many studies purporting to demonstrate this effect. The review concludes that there is no evidence to support the use of phenothi-

azines as narcotic potentiators, and also questions the prophylactic use of these drugs to prevent narcotic induced nausea.

The value of the alcohol in the mixture is questionable. One group found that it had no influence on pain relief or side effects, but did find that solutions without alcohol grew cloudy in one week. Cloudiness could be prevented by adding alcohol at a concentration of 7.4%. Some have questioned the inclusion of high quantities of alcohol as it gives the mixture a characteristic "bite" which is quite unpleasant to patients with oral or pharangeal lesions.

There has remained much controversy concerning the opiate of choice, with several authorities calling for the legalization of heroin for this purpose. Such a bill was introduced and defeated in Congress in 1984. Several randomized, controlled, crossover trials comparing heroin and morphine in terminal cancer patients have been reported. In one, morphine and heroin were titrated to equi-analgesic doses and were compared for the incidence and severity of side effects. The potency ratio for heroin to morphine was 1.5:1. No significant differences in ability to control pain or in side effects were noted.

It was concluded that providing allowance was made for the difference in potency, there is no difference between them when given regularly by mouth. A more recent trial found no apparent advantages or disadvantages for either in the relief of pain due to cancer.

Based on these findings, the following suggestions for the use of narcotics in the treatment of chronic cancer pain are suggested:

- 1) Oral narcotics are preferred over parenteral forms due to their lower cost, ease of administration, and to avoid the problems associated with repeated injections in cachectic, suffering, terminally ill patients. Oral dosing makes home administration much easier and can significantly reduce the need for repeated visits by nurses.
- 2) Morphine, due to its lower cost, water solubility, and pharmacokinetics, is the preferred oral analgesic.
- 3) Cocaine should not be routinely added to the mixture, this will greatly reduce the compounding and regulatory problems associated with the mixture. Patients with persistent, troublesome sedation may be given cocaine and the benefits should be assessed regularly.
- 4) Ethyl alcohol should only be added at a concentration sufficient to act as a preservative and flavoring agent (8–10% of the mixture) due to problems with taste and additive CNS depression.
- 5) Phenothiazines should not be used with the intent of potentiating pain relief. If needed to counteract nausea, particularly in the initial weeks of therapy, prochlorperazine should be prescribed and dosed according to need, (5–10 mg q 4–6 h),



Morphine

but should *not*, for reasons of stability and flexibility, be added to the mixture.

- 6) An unflavored, morphine-alcohol elixir is commercially available which contains 10 mg. morphine/5 ml and 10% alcohol. This can be used and added to juices or foods. Morphine/alcohol elixirs can also be prepared extemporaneously in virtually any morphine concentration and any flavoring/coloring and additive adjustment made to suit individual needs. Morphine sulfate is sufficiently soluble in water, (62.5 mg/ml), to allow doses of much smaller volume to be used than the standard 20 ml. dose. This may be of value in patients with swallowing difficulties and may make it easier to disguise the taste in foods and juices. The addition of alcohol and flavorings will reduce the solubility of morphine. However, virtually any dose can probably be contained in 5 ml.
- 7) Dosing considerations:
- a) In the elderly begin with a 4-hourly dose of morphine of 2.5 mg. and increase as needed at 48–72 hour intervals to sequential doses of 5, 10, 15, 20, 30, 40, 60, 90, and 120 mg. Younger patients, or those in more severe pain, may be started with 5–10 mg. doses. *Most* patients can be controlled with doses of 5–20 mg. every 4 hours.
- b) Dose *regularly*, every 4 hours around the clock, omitting nighttime doses only when the patient can sleep, pain-free throughout the night. Patients may need every hour or occasionally every 3 hours to control the pain.
- c) If using cocaine or phenothiazines, adjust only one variable at a time.
- d) The use of supplemental analgesics should be considered while awaiting the full response from

- the current dose rather than increasing the base solution more frequently than every 48–72 hours. If supplemental analgesia is needed, morphine sulfate is given parenterally in dose of one-half of current oral dose.
- e) Initiation of therapy will usually produce transient sedation lasting 48–72 hours. It is important to reassure both the patient and family that this is only transient and that pain can and will ultimately be controlled without undue sedation. The patient's confidence that control will be achieved will potentiate analgesia.
- f) Careful observation over a 24 hour period may suggest augmentation of one or two specific doses at periods of peak activity.
- g) The maximal effective oral dose of morphine is ill-defined, but it has been suggested that increased relief may be obtained with doses as high as 120 mg. Again, most patients can be controlled on much less.
- h) Constipation must be anticipated and prevented.
- i) Complete attention must be paid to the total medical, surgical, financial, and psychological needs of the patient. The response to the mixture is achieved when attention is paid to these details.

Other opiates can also be used if needed, but none offer an important advantage over oral morphine. Meperidine is unsuitable for chronic dosing because of a very short duration and a high incidence of CNS side effects. Codeine is likely to cause severe constipation. Methadone has a longer duration of action than morphine and can often be dosed every six and every eight hours, but due to its long serum half life, significant accumulation can occur with frequent dosage changes. Potency is not a factor, as it only determines how much drug must be given to achieve similar effects. If the patient is allergic to morphine or has a dysphoric reaction to it or a similar agent, a member of a chemically distinct class may be used such as methadone or meperidine. If necessary, due to a patient's inability to swallow, other routes of administration must be used. Morphine can be given rectally, parenterally (IV, IM, SQ) and intrathecally. Some Hospice centers have had favorable results with morphine given by continuous intravenous infusion. They have noted improved pain control with a lower total dose and with fewer side effects, but this procedure is not easily performed on an outpatient basis. Some work has also been done on patient controlled analgesia where the patient has the ability to augment, when needed, as basal rate of morphine infusion. This is still in the experimental stage however.

The pharmacist is most expert in providing equivalency data if route or drug changes become necessary. It must be kept in mind, when using the many available data, that much may be based on acute dosing, and may not apply to chronic dosing. Thus, the oral to parenteral ratio for morphine with chronic dosing is about 2 to 1 rather than the often listed 6 to 1. The implications of these considerations can be considerable. The pharmacist is often called upon when a patient cannot swallow or tolerate the prescribed medication. A thorough knowledge of solubilities, taste, and stability considerations can be of immense benefit to the patient, particularly if such information can be put to use to avoid the need to go to parenteral medications.

In certain patients, pain control may still be difficult despite optimal use of narcotic analgesics. Other approaches that may be tried include; Transcutaneous Electroneuronal Stimulation (TENS), surgery (ie—nerve block), palliative radiation to relieve obstruction of inflammation, and even palliative chemotherapy. There may also augment pain relief in patients responding to narcotic analgesics. Tricyclic antidepressants may be effective against both the depression caused by severe prolonged pain and the pain itself.

With the emphasis on narcotic analgesics, it must not be forgotten that some patients may experience significant relief with non-narcotic agents such as aspirin and acetaminophen. These agents have important analgesic properties and in controlled studies were equal or superior to the usual doses of codeine, epntazocine, and propoxyphene. Many patients with cancer may have only mild pain and may need only acetaminophen. When pain becomes more severe, the addition of a narcotic analgesic can result in synergistic effects, thus many patients may benefit from the use of such drugs. Although equipotent as analgesics, acetaminophen is usually better tolerated with chronic dosing.

Although pain is of major concern, terminally ill patients also experience many other problems which can be noted by and dealt with by a concerned pharmacist. The pharmacist should recognize that narcotic analgesics regularly cause constipation and that this is best prevented rather than reacted to. The usual recommendations of increased fluid intake, stool softeners, and bulking reagents may be helpful, but in narcotic-induced constipation, a stimulant laxative such as senna is often necessary. These can be dosed regularly as tolerated to prevent impaction. The patient with dysphagia presented a special challenge for the pharmacist. The use of small volumes of liquid medications with a low alcohol concentration can help the patient to continue on oral medications. Oral lidocaine in a viscous solution may alleviate pain in patients with oral lesions. The pharmacist's drug history can identify other drugs which may be implicated in the genesis of other symptomatology. Anorexia may be decreased by small doses of corticosteroids and by the control of nausea. Dyspnea is common in the final stages of neoplastic disease. Morphine can then be given parenterally and will alleviate anxiety and suffering. Although this can depress respirations, this may be an acceptable risk for the benefit of the patient in the interest of easing suffering. Its

use in this context should be understood as such by all, to avoid concern and doubts among the nursing staff who must administer the medication as ordered.

Much progress has been made in our understanding of the terminally ill patient, and in our ability to offer effective measures to enhance the final days of these patients. We have come a long way since the days when the typical reaction was "nothing more can be done". Undoubtedly our understanding will continue to increase in the future as the hospice concept takes hold in America, and as we gain even more experience. The pharmacist can and should have a significant role in this process.

SUGGESTED READING

- DuBois, PM: The Hospice Way of Death. Human Sciences Press, New York, 1980
- Saunders C., Summers DH, Teller N (eds): Hospice: The Living Idea. WB Saunders, Philadelphia, 1981
- 3. DeBellis R., Goldberg IK, Kutscher AH, Blitzer A., Gerber I., Tretter O (eds): *Medical Care of the Dying Patient*. Arno Press, New York, 1982
- 4. Corr, CA, Corr, DM (eds): Hospice Care: Principles and Practice. Springer Publ. Co., New York, 1983
- Munley, Anne: The Hospice Alternative. Basic Books, Inc. New York, 1983

PHARMACISTS JOIN HEALTHY MAJORITY

The Maryland Pharmaceutical Association has joined the Healthy Majority. This coalition of health minded professional organizations and individuals has come together for the past two years to seek passage of statewide legislation that would provide smoking and no smoking sections in restaurants, retail stores, and other public places. The evidence is overwhelming Secondhand smoke from other people's cigarettes is an irritant and potential health risk for non-smokers, especially children.

Coalition membership includes the Cancer, Heart and Lung Associations, Med Chi, the Md. Nurses Association, the YMCA and the Public Health Assn. among others. There are over 3000 individual members across the State. Now is the time to phone or write your legislator and express your support for clean indoor AIR bills. Keep reading the monthly newsletter articles regarding the activities of the Healthy Majority.

Meetings are being held with legislators around the state asking for their support. If you would like to participate in these meetings or if you just want additional information on the issue, please contact Robin Shaivitz, Community Coordinator for the Healthy Majority at (301) 685-7074.

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Standing Left to Right:

John Piecoro, Jr., Pharm. D. Clinical Pharmacist University of Kentucky Lexington, Kentucky

Seated Left to Right:

Charles Lippert, R.Ph. Community Pharmacist Zeeland, Michigan Reed Rosling, R.Ph. Vice President, Hospital Sales Bergen Brunswig Drug Co. Orange, California

William Thien, R.Ph. Director, Health Services & Pharmacy Operations Walgreen Drug Stores Deerfield, Illinois

John Kogut, R.Ph. Vice President Fay's Drug Company Liverpool, New York

Carl Lyons, R.Ph. Institutional Pharmacist Tulsa, Oklahoma Larry Braden, R.Ph. Executive Vice President Georgia Pharmaceutical Association Atlanta, Georgia

Lonnie Hollingsworth, R.Ph. Community Pharmacist Lubbock, Texas Marily Rhudy, R.Ph. Community Pharmacist Topeka, Kansas

Bernard Mehl, R.Ph. Director of Pharmacy Mount Sinai Hospital New York, New York

Not pictured: John Colaizzi, Ph.D., Dean, College of Pharmacy, Rutgers University, Piscataway, New Jersey

Upjohn

national scene

Warning on Ipecac



Home Health Care



Ads Target Pharmacists



Drugs and the Elderly



Syrup of ipecac is used successfully to treat some 150,000 cases of acute poison ingestion a year, but this readily available drug has a less beneficial side as well—it is suspected of being misused by up to 30,000 young women who suffer from the eating disorder bulimia and use the product to induce vomiting after episodes of binge eating. Pharmacists should remember that one of the active ingredients in ipecac, emetine, can pro-

duce irreversible damage to heart muscle, and even heart attack, when ipecac is used on a chronic basis. A typical dose for bulimics is a whopping three to four 1-ounce bottles a day. Any patients (especially young females) who are buying ipecac in large quantities should be referred to a physician right away. Other signs of abuse to watch for are shortness of breath, low blood pressure, and irregularities in heart beat.

Newly released regulations from the U.S. Department of Health and Human Resources appear likely to limit the number of people who can benefit from home health care services under Medicaid. The new rules reflect Reagan Administration fears that new home health care programs established to assist those who would otherwise have to live in a nursing home would also attract great numbers of people who had previously been re-

ceiving no benefits. Thus, the Administration says, providing new home health care benefits to people who do not need them would simply create a new federal medical expense instead of replacing costly nursing home care. Currently, nearly half of all Medicaid funds are spent for nursing home care. In FY 1983, the federal and state governments spent \$14.1 billion under Medicaid to provide nursing home care to 1.5 million people.

A new survey of pharmaceutical advertising trends shows that pharmacists will increasingly become the recipients of carefully targeted mass mailings from drug manufacturers, while the number of such ads to nurses and physician assistants will drop. The companies report they increasingly see pharmacists as important decision-makers in terms of drug

product selection and getting new products into formularies. The large number of major drugs going off patent over the next few years will add to the number of generic products the pharmacist will be stocking, and the companies predict that the pharmacist will play an ever larger role in determining which product gets into the hands of the consumer.

Prescription drugs are taking less and less of the elderly person's income, according to new information from the Food and Drug Administration. In 1970, these drugs cost 2.4% of the elderly person's income, compared with only 1.0% in 1980. The elderly person is also paying a smaller portion of drug costs themselves. In 1970, "private sources" (insurance and out-of-pocket) funds paid for 88%. By 1980, this percentage had de-

clined to just over 82%—with a full 68% of this coming from insurance. But even though the elderly are paying less, they are using prescription drugs to a greater extent than ever before. In 1967, less than 70% of this population consumed prescription drugs; by 1980, the figure had jumped to more than 80% and the average number of prescriptions by beneficiary was 12.1.



1984 Hospital Pharmacy Operations

Selected operating data from 1,964 hospital pharmacies are shown in Table 1. These reflect a composite profile of the "average" hospital pharmacy in the United States for the operating year 1984. Since this hypothetical hospital pharmacy is derived mathematically from a broad range of information, the figures may be too general to permit direct comparison with those of your operation. However, trends can be observed by comparing the figures with similar statistics published in previous issues of the *Lilly Hospital Pharmacy Survey*.

Table 1 shows that the average hospital in 1984 had 245 beds—essentially unchanged from 1983 and the same as the number reported for 1982. Of particular note was the dramatic decline in census (from 69 percent in 1983 to 63 percent in 1984). Census has fallen consistently since 1982, and the 1984 level is more than 10 percentage points below the average annual census rate of 73.5 percent observed from 1975 through 1981. Admissions during 1984 were 2 percent lower than in the previous year.

The average length of hospital stay declined from 7.1 days last year to 6.6 days in 1984 (a decrease of one-half day), the shortest period of patient stay ever recorded in the *Survey*. The largest segment of hospitals reporting to the *Survey* continues to be private (non-profit), general institutions.

Both the number of hours the central pharmacy was open as well as the number of hours worked by pharmacists rose slightly during 1984, although technician and support personnel hours somewhat declined. Overall, the total hours worked per week by the staff remained virtually unchanged from the previous year. Three hours of pharmacist time were required for each hour the central pharmacy was open during 1984—slightly higher than the 2.9 reported last year. The ratio of hours worked by technicians to hours open was approximately the same as reported the previous year—2.7. Hours worked by support personnel for every hour open declined from 1.2 to 1.1 during 1984.

For the first time in *Survey* history, the dollar value of inventory in 1984 did not show an increase over the previous year's figure. However, purchases were over 7 percent higher, with the result that estimated inventory turnover rate increased from 7.2 to 7.8 times. Had the inventory turnover rate remained at 7.2 times during 1984, inventory would have been about \$10,000 higher than the 1983 figure. It should be noted that, figured on

the basis of occupied beds, inventory and purchases figures were approximately 10 and 18 percent higher, respectively, than in 1983. The significant improvement in the inventory turnover rate observed over the past few years indicates that hospital pharmacy managers are continuing to succeed in their efforts to control inventory investment, which contributes to better cash flow in their institutions.

Comparison of inventory and purchases based on patient days shows that inventory during 1984 equaled \$2.16 per patient day—up 20 cents—or 10.2 percent higher than in the previous year. Purchases were \$16.77 per patient day, an increase of 18.2 percent. Because inflation is not taken into account, its influence on inventory and purchases cannot be isolated. Therefore, these figures do not necessarily reflect increased use of drugs and related items by hospital patients.

Among the ten services listed in the *Survey*, the ranking for the top four was the same for 1984 as for 1983. These four services were offered by over 60 percent of hospital pharmacies that responded. Interestingly, pharmacokinetic service, although not ranked among the top four, showed the highest rate of growth—from 23.2 percent in 1983 to 27.7 percent in 1984. These data suggest that clinical services offered in reporting hospital pharmacies continue to expand.

A comparison of selected operating statistics over the nine years that the *Lilly Hospital Pharmacy Survey* has been published reveals the following trends:

- —Pharmacy hours open per week rose from 74 to 97, an increase of 31.1 percent.
- —Pharmacist hours worked per week increased 90.8 percent, from 152 to 290, or approximately 10 percent each year.
- —Although technician hours worked per week fluctuated from year to year, they trended upward from 129 to 260, a 101.6 percent increase, or about 11 percent each year.
- —Inventory investment rose 76.9 percent, an annual growth rate of about 8 percent over the nine-year period. Inventory per occupied bed increased 118.3 percent, for an annual rate of over 13 percent.
- —Purchases increased 190.3 percent during this period, for an annual growth rate of over 21 percent. Purchases per occupied bed went up 258.8 percent, reflecting an annual rate of 28.8 percent.

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—\$.02 per coupon; 500 to 1000 coupons—\$.02.5 per coupon; and batches of 1000 coupons and over—\$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.



Table 1
Average Hospital Pharmacy
Preliminary Report

	1984 (1964 Hospitals)		Percent of Change	
Bed capacity	245	246	-0.4%	
Class	private/	private/	0. + /0	
	nonprofit/general	nonprofit/general		
Census (occupied beds)	63%	69%		
Admissions	8582	8750	-2.0%	
Patient days	56,338	61,955	2.078	
Length of stay	6.6 days	7.1 days		
Hours central pharmacy open/week	97	96	+1.0%	
Pharmacist hours/week	290 (7.3 FTE)	281 (7.0 FTE)	+3.2%	
Technician hours/week	260 (6.5 FTE)	263 (6.6 FTE)	-1.2%	
Support personnel hours/week	109 (2.7 FTE)	116 (2.9 FTE)	-6.4%	
Inventory	\$121,414	\$121,552	-0.1%	
	\$ 2.16/patient day	\$ 1.96/patient day	+10.2%	
	\$ 496/bed	\$ 494/bed	+0.4%	
	\$ 786/occupied bed	\$ 715/occupied bed	+9.9%	
Durcheses	\$14.15/admission	\$13.89/admission	+1.9%	
Purchases	\$944,569	\$879,431	+7.4%	
	\$16.77/patient day	\$14.19/patient day	+18.2%	
	\$ 3855/bed	\$ 3575/bed	+7.8%	
	\$ 6118/occupied bed	\$ 5181/occupied bed	+18.1%	
Inventory turneyer rate	\$110.06/admission	\$100.51/admission	+9.9%	
Inventory turnover rate	7.8 times	7.2 times		
Floor area (central pharmacy)	1734 sq ft	1629 sq ft		
Services offered by over 60% of pharmacies:	8.6 m m 24	Andrew water A 601		
Monitoring patient profiles Monitoring drug interactions		toring patient profiles		
Providing drug information service	Monii	toring drug interactions		
Drug therapy consultation		ding drug information services		
Drug therapy consultation	Drug	therapy consultation		

Some Thoughts on Handling Questions About Drugs of Abuse

Tony Tommasello

Pharmacists are frequently asked about drugs of abuse. Questions of street drug identity, pharmacological effects of drugs, and adolescent drug abuse intervention are likely to come up in a practice setting. Being the health professional recognized as the drug expert, it is important that we respond to these inquiries appropriately. In answering these questions one must consider that the individual isn't able to express their concerns forthrightly. For instance, rather than saying she is concerned about her daughter's marihuana abuse, a mother might ask about the health problems associated with marihuana smoking. As pharmacists occupying a front line position on the health care team, it is fitting for us to think of these interactions as opportunities to exercise our clinical training and maximize the patient's benefit resulting from this exchange.

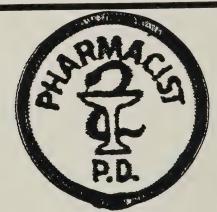
The illicit channels of drug distribution make identification of specific samples impossible except through an exact chemical determination. This is obvious if the item in question is a powder or some vague botanical sample. But it is also true of tablets and capsules. Street drug testing services have documented cases of tablet forgery. Capsules can be taken apart and refilled. When a parent brings a drug sample to a pharmacy for identification it is prudent to bring this to light. A more important element in this type of question is where did the parent find this unknown item and what makes them believe it is a drug of abuse. In most cases this will allow the parent to describe their child's recent unusual behavior which is typical of drug abuse involvement. Once the real issue is on the table a reasonable course of action can be recommended.

Superficial questions about the effects of drugs of abuse similarly mask an underlying concern about someone's drug involvement. While it is tempting to simply display our knowledge of pharmacology, doing so does little to allay the concerns of the individual and offers no resolution to the real problem at hand. After answering the question with pharmacological fact a simple inquiry such as: "Is there someone whom you are concerned about?", will often bring out the real issue. Once again a reasonable course of action can then be suggested.

In the rare instance of having a question put in terms of treatment resource availability there is the possibility once again that the individual is misdirected. They may ask if you know of any hospitals that offer drug abuse

treatment. We must be prepared to dig a little deeper into the particulars of the case. The individual may not be in a position of being able to assess the differences between inpatient and outpatient care. They may be unable to see the need for a broad range of services because they are microscopically focused on a recent crisis. As health professionals we must have a greater understanding of treatment resources, the services each offers, and the applicability of these services to the case at hand. Finally we should be able to offer specific resource recommendations which requires a knowledge of the local availability of drug abuse treatment services.

Drug abuse intervention is a challenging new area for pharmacist involvement in community health. It is equally important for us to realize that alcoholism and chemical dependence are conditions that can affect us all. We must be equally prepared to extend our concern to our colleagues in the event of their impairment during the course of their professional career.



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DRUG ABUSE

The Pharmacist's Role in Public Education

he retail pharmacist is the most accessible health care professional in the community. Parents and their children often turn to their pharmacist to ask questions or get advice about drug abuse in addition to information on prescription and OTC medications. Patient counseling is a hallmark of independent community practice, but pharmacists in virtually all settings often find themselves sought out by individuals concerned about chemical substances, particularly those subject to abuse.

Drug abuse is a killer. It threatens to destroy the health and well-being of millions in the United States—the nation with the greatest incidence of drug abuse in the world. While alcohol and drug abuse has become a major health issue in our society, the problem is not one-dimensional. During the course of NARD's campaign for pharmacy crime legislation, the association found that between 1976 and 1981 pharmacy robberies involving controlled substances increased by 113 percent. Robberies of all types increased by only one-third. The problem is truly at our doorstep.

DRUG EXPERTS

Pharmacists have a significant opportunity to play a key role in the war on drug abuse. "No one is better informed and in a better position to talk to the public about drugs than the pharmacist," says drug abuse authority Sidney Cohen, M.D. "Although they have never dispensed many of the chemicals that are matters of concern these days, the pharmacist's training has provided a basis for understanding such strange, nonmedical substances as phenycyclidine, LSD, and mescaline. As to the various sedatives, stimulants, and narcotics, the pharmacist's practical knowledge of effects, side effects, tolerance, and withdrawal probably exceeds

that of any health professional." Dr. Cohen points out that pharmacists, "informed with correct, up-to-date information, can help those individuals and families who are troubled, confused, and do not know where to turn. The pharmacist can act as a gatekeeper: reassuring some, pointing out dangers to others, and referring those who need it to appropriate community resources."

EDUCATION

Dr. Cohen's emphasis on up-to-date information is the basis of a drug abuse program produced by NARD with major support from Eli Lilly and Company. The NARD Drug Abuse Program, of which Dr. Cohen is a co-author, is a self-instructional, continuing pharmacy education program. It is accredited for eight CE hours in all states that accept the ACPE-approved provider system, as well as in Alabama, Minnesota, and Oklahoma.

The core of the program is a 104-page book that includes an overview of alcohol and drug abuse in the U.S., abuse of legal drugs, profiles of drug abusers, and strategies for prevention and treatment involving community, family, and school settings. Pharmacists may also borrow an audiovisual presentation on drug abuse, available in a variety of popular formats from NARD. Many pharmacists use this presentation before service and civic organizations in their communities.

For the cost of an envelope and a 22-cent stamp you can join the fight. The CE book is available free from NARD, 205 Daingerfield Road, Alexandria, VA 22314. What we are really asking you to invest in is your community, by applying your special expertise in helping to combat an insidious problem—drug abuse.

FYI, a monthly perspective on topics of interest to pharmacists, is provided as a service by the National Association of Retail Druggists.

Give the Answers!

By anticipating your patients' questions on drugs and answering them even before they are asked, you can assert, all the more strongly, the pharmacist's appropriate role in patient drug education and community health.

The National Council on Patient Information and Education (NCPIE) campaign, "I Give the Answers," is now in full swing. They are asking you to assert your traditional leadership and to demonstrate your personal commitment in this vital area by answering your patients' question as you always do, and by providing answers even when your patients don't, but should ask questions on their medicines, so that they are taken safely and effectively.

NCPIE strongly recommends that every patient know:

- 1. The name of the medicine and what it is supposed to do.
- How and when to take the medicine, and for how long.
- The food, drinks, other medicines, and activities to be avoided while taking this medicine.
- 4. The possible side effects, and what the patient should do if they occur.
- 5. What written information about the medicine is available to them.

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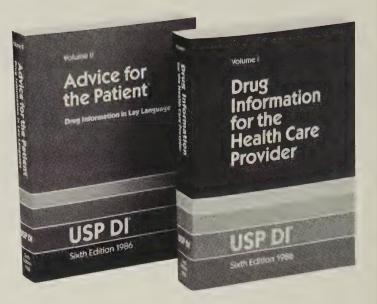
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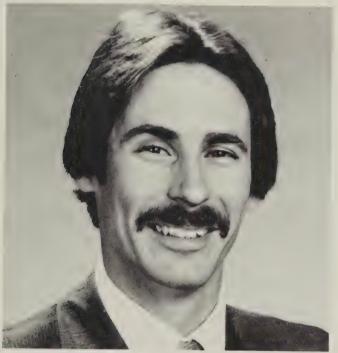
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MPhA Board Members Elwin Alpern (left) and Martin Mintz (right) visited the Chemistry Lab named for the Baltimore Metropolitan Pharmaceutical Association in the new Pharmacy School building. If you have not yet toured the new building, call the School to arrange a visit.



MPhA Member, Gary Magnus, sent us this picture of the damage from hurricane Gloria to the Carousel Hotel in Ocean City, Maryland. The successful 1985 MPhA Convention was held in the Carousel. The 1986 Convention has been moved to the Sheraton Hotel; also in Ocean City.



Donald E. Ewalt has completed a five month training program with Syntex and has been assigned to the Maryland area as a medical representative.



Marvin Freedenberg, the MPhA's 1985 Bowl of Hygeia Award winner for outstanding community service, had an opportunity to tour the A. H. Robins Company in Richmond Virginia. Marvin was recently appointed to the Board of Directors of the American Cancer Society.

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

DIGOXIN ABSORPTION:

The bioavailability of digoxin (Lanoxin) can be altered by a variety of substances and conditions. The dissolution rate of the digoxin tablet is inversely related to the size of the digoxin particles and absorption increases as motility decreases. Drugs such as metoclopramide (Reglan), propantheline (Probanthine), diphenoxylate-atropine (Lomotil), etc. can increase the time needed for the cardiac glycoside to reach its peak plasma level. The effect is less dramatic if the digoxin capsule (Lanocap) is used because the drug is already in soluble form. *Clin Pharmacol Ther*, Vol. 36, #6, p. 724, 1984.

LUPUS-INDUCED NEPHROSIS:

Patients who succomb to complications of systemic lupus erythematosus most frequently experience severe renal failure. In the past, steroids have been used to minimize renal damage, and the addition of an immunosuppressant was thought to offer no additional benefit to the steroidal therapy. New information suggests that the conclusion reached from previous work was inaccurate due to subminimal sample size. These authors feel strongly that the addition of an immunosuppressant agent such as cyclophosphamide or azathioprine significantly improves the condition of patients experiencing renal complication of this condition. *N Engl J Med*, Vol. 311, #24, p. 1528, 1984.

INSULIN REACTIONS:

Excessive insulin can lead to profound hypoglycemia. This is often referred to as insulin reaction and requires a readily available source of carbohydrate to elevate the glucose level in the plasma. Patients with severe hypoglycemia were given glucose in the form of glucose tables, milk and orange juice to see which might be most useful in these types of emergencies. Although the glucose tablets produce results comparable to those obtained when the patient consumed 40 grams of carbohydrate in the form of 12 ounces of orange juice, the authors of this article suggest that orange juice be considered as first line therapy because it is more readily available and easier to take than glucose tables. *JAMA*, Vol. 252, #24, p. 3378, 1984.

ADENOSINE RECEPTORS:

Adenosine was found to inhibit the secretion of acid by the stomach, while theophylline produces the opposite effect. The action of adenosine is apparently on the Ri receptor located in the stomach. Although adenosine prevents histaminergic and cholinergic-induced acid secretion, its effects are inhibited by low doses of the xanthine derivative. This suggests that the role of theophylline in stimulating gastric acid secretion is independent of its role in the inhibition of phosphodiesterase degradation. Adenosine inhibits adenyl cyclase activity, thus reducing acid secretion. Additional work shows that adenosine can inhibit H-2 and beta adrenergic activation of certain receptors in the heart thus unmasking the cardiac response to H-1 and alpha agonists. *J Pharmacol Exp Ther*, Vol. 231, #2, p. 109, p. 215, 1984.

CHILDBEARING:

Women in Sweden were studied to determine the health of newborn in contrast to maternal age at delivery. The general medical care in Sweden is quite good and is comparable to that found in the United States. In both countries, however, there is an increase in the incidence of stillbirth/premature infants. This is said to be associated with the age of the mother and is most serious between maternal ages of 35 and 39 years. *JAMA*, Vol. 252, #22, p. 3135, 1984.

ACETAMINOPHEN TOXICITY:

The administration of acetaminophen (Tylenol) to mice has demonstrated the presence of a sex-related increase in sensitivity to its lethal effect. Male animals seemed to be more resistant to the lethal effect of the analgesic as reflected by a greater LD-50 dose. Enzymatic studies show that males also have less alteration in serum enzymes. No evidence has been accumulated to suggest that the same variations occur in humans. Clin Toxicol, Vol. 22, #2, p. 149, 1984.

ORAL CONTRACEPTIVES AND BENZODIAZEPINE DERIVATIVES:

The administration of oral contraceptives has been shown to alter the activity of various drug products. The estrogens can inhibit the oxidative metabolism of theophylline, caffeine, diazepam, and chlordiazepoxide. On the other hand, glucuronidation of suitable substrate is enhanced in the presence of oral contraceptives and a reduction in the efficacy of acetaminophen has been noted to occur. Several of the newer benzodiazepine derivatives have been evaluated in the presence of the oral contraceptives to determine the possibility of significant interactions. The triazolobenzodiazepine derivatives, alprazolam and triazolam, seem to have increased duration of action in the presence of the estrogen. This increased half-life is apparently due to estrogen-induced inhibition in the oxidative metabolism of these agents. Glucuronidation, as stimulated in the presence of estrogens, may result in the reduced half-life of both lorazepam and temazepam. Clin Pharmacol Ther, Vol. 36, #5, p. 683, 1984.

Patient Aid

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

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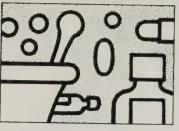
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Things You Should Know FOR YOUR GOOD HEALTH



Start Off the New Year with Some Wise Habits

There is no better time to think about our health than at the beginning of a new year. Several recommendations are given in the book "Healthy People — The Surgeon General's Report on Health Promotion and Disease Prevention" (U.S. Government, 1979):

- 1. Smoking: It is suggested that people stop smoking or, if not possible, smoke brands low in tar and nicotine, inhale less, smoke cigarettes only half way, and gradually reduce the number smoked.
- 2. Alcohol: Individuals with problems related to alcohol may find assistance from health professionals, the clergy, community groups such as Alcoholics Anonymous, or programs run by various businesses to assist employees.
- 3. Nutrition: People should consume only sufficient calories to meet body needs (less if overweight); less saturated fat, cholesterol, salt, sugar; more bulk such as whole grain cereals, fruits and vegetables; more poultry, fish and legumes in preference to red meat.
- 4. Exercise: Adults should build up to exercising at least three times a week for 15 to 30 minutes each time. People over age 40 should develop an exercise plan cautiously.
- 5. Work Site Health and Safety: Individuals should encourage health programs at the work site and take advantage of them.
- 6. Hypertension: Adults should be screened for high blood pressure at least once every five years (every two or three years if over age 40).

- 7. Pap Smear: Women should have three pap smears taken one year apart beginning at age 20, or at the beginning of sexual activity. Thereafter, a pap smear should be taken every three years. Women receiving oral contraceptives or estrogens should be screened more frequently.
- 8. Breast Examination: Women should examine their own breasts monthly after the menstrual period for early signs of cancer (lumps, abnormal discharge, irregular size). Self-examination is the most effective way to detect breast cancer in the early treatable stage.
- 9. Cancer Signs: People should watch for early signs of cancer and consult a physician if any are noticed. The seven signs, according to the American Cancer Society, are: 1) those noted above for the breasts, 2) changes in bowel or bladder habits, 3) a sore that does not heal, 4) unusual bleeding or discharge, 5) difficulty swallowing, 6) change in a wart or mole, and 7) nagging cough or horseness.
- 10. Dental Care: Adults should take care of their teeth with daily brushing and flossing and an annual dental exam.
- 11. Mental Health: It is quite common for people to become, at one time or another, uncommonly anxious, depressed, or to have difficulty coping with a life event. Professional assistance may be helpful and is available through many sources.
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STAFF PHARMACIST

Come practice with us! Memorial Hospital of Natrona County is a 282 bed JCAH accredited acute care hospital located in Central Wyoming. We are currently seeking a qualified individual for the position of staff pharmacist. Applicants shall possess a minimum of a B.S. degree and hospital experience is preferred. Duties will include centralized distributive activities, IV admixture, and TPN preparation. We are also in the process of planning for 24 hour unit dose distribution with decentralized pharmacy service.

Memorial Hospital offers a competitive salary and benefit package. The Casper area also offers a wide variety of extracurricular activities from which to choose. These include hunting, fishing, skiing, and symphony presentations. Interested parties should send an updated resume with at least 3 references to: Betty Snyder, Personnel Department Memorial Hospital of Natrona County, 1233 East 2nd Street, Casper, Wyoming 82601.

Pharmacy position: Full time pharmacist needed. Excellent salary and benefits. In a new and growing pharmacy. Send resume to: Box 65129, Baltimore, Maryland 21209

DIABETES CE PROGRAM-A NEW APPROACH

The CECC diabetes program "Diabetes" to be presented in May, 1986, will have a unique format that will enable material presented to be readily adapted into pharmacy practice. CE generally provides the information pharmacists should know in order to practice. However, limited time is available to teach them how to integrate knowledge into practice. The May participants will receive the factual information in advance. The program itself will then concentrate on using this knowledge in practice. Small group and/or workshop formats will be utilized where possible to facilitate student/instructor interactions. Detailed information regarding this program will be forthcoming shortly.

For information contact:

Marvin L. Oed 528-7118

Hotline for Impaired Pharmacists (301) 727-0746
FDA Hotline for AIDS 800-342-AIDS
Hotline for impaired Physicians (301) 467-4224
Hotline for impaired Dentists (301) 796-8441

The Baltimore Veteran Druggists' Association (organized 1926) meets every third Wednesday of the month at Duff's famous smorgasbord on Westview Mall Road Beltway Exit No. 15A. For further information contact President Frank Block (phone: 358-2743).

Central Michigan University has announced plans for a Master of Science in Administration degree with a concentration in Health Services Administration at Aberdeen Proving Ground, Maryland.

The graduate degree program is identical to those offered at Andrews Air Force Base and Fort Meade, Maryland, at Walter Reed Army Medical Center in Washington, and at the hospitals in Hawaii, Illinois, Michigan and North Carolina. National sponsors include the American Heart Association, The American Lung Association, The American Society for Medical Technology and the American Society for Respiratory Therapy. Since 1972, more than 18,000 professional adults have earned a master's degree from CMU through an off-campus program, 3,000 of them in Health Services Administration.

CMU schedules courses at Aberdeen on a weekend format. Classes meet on Friday evenings, Saturday, and Sunday of alternate weekends. A total of 36 semester hours of credit are required for the MSA degree. Stu-

dents complete 12 to 18 semester hours of General Administration courses, 12 to 18 hours of study in Health Services Administration, and a final integrating experience of six hours in which they apply knowledge acquired in the classroom to their own professional Health Services positions.

An academic advisor is available by appointment to assist students in structuring programs with CMU. The advisor also offers guidance to students who wish to utilize the options of graduate transfer credit and credit for relevant job and training experience.

Also, CMU's comprehensive library and research support services are provided full-time by a professional regional librarian and by toll-free telephone access to the campus library.

CMU can accept no more than 30 applications for this pilot program. For more information or an appointment with a CMU representative, interested persons may call (301) 272-1532, Shirley Geurts or (703) 849-8219, Dianne Turpin.

